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THE FUTURE OF ALZHEIMER'S BREAKTHROUGHS AND CHALLENGES

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THE FUTURE OF ALZHEIMER'S: BREAKTHROUGHS AND CHALLENGES

Wednesday, May 14, 2008

U.S. SENATE
SPECIAL COMMITTEE ON AGING
Washington, D.C.

The committee met, pursuant to notice, at 10:44 a.m. in room SD–106, Dirksen Senate Office Building, Hon. Herb Kohl (chairman of the committee) presiding.

Present: Senators Kohl, Wyden, Lincoln, Carper, Salazar, Whitehouse, Smith, Collins, Dole, Coleman, and Corker.

OPENING STATEMENT OF SENATOR HERB KOHL, CHAIRMAN

The CHAIRMAN. Good morning to you all, and we thank you for being with us here today.

We would particularly like to express appreciation to our esteemed panel of witnesses for their willingness to participate in this hearing. Today, we will be discussing Alzheimer's, a disease that currently affects over 5 million Americans and their families and is anticipated to affect millions more as our population ages.

Without a cure or at least some treatment to delay the progression of Alzheimer's, there will be almost a half million new cases each year by 2010. So, clearly, Alzheimer's disease is a growing national crisis, and we must commit to addressing it in the most comprehensive way possible. There are enormous costs, both personal and financial. That is why we need to prepare for this mounting epidemic and to determine in what capacity we are able to curb it.

Right off the bat, we know that there are three things Congress can do and has done this year. The first is to increase funding for research to find cures or treatments that will slow the onset of this disease. The second is to provide support to individuals and their families that are living with the disease. Finally, we can protect those with genetic predisposition to this and other diseases from discrimination by their workplace or insurer.

Legislation exists or will shortly be introduced to address all three of these action issues. For instance, the Alzheimer's Breakthrough Act aims to increase research funding. The bill, introduced by my colleagues Senator Mikulski, Senator Bond, Senator Clinton, and Senator Collins, would double funding for Alzheimer's research at the National Institutes for Health to $1.3 billion. This bill passed through the HELP Committee in July of last year and is currently awaiting a vote.

Recently, I announced a plan to introduce legislation that would offer training and support services to family caregivers. Almost 10

million Americans are caring for a person with Alzheimer's disease or other dementias. These caregivers frequently do the same work as a professional caregiver, but they do so voluntarily and with little or no training or access to broader support services.

Finally, I am happy to say that the Genetic Information Nondiscrimination Act recently passed both the House with only one no vote and the Senate with unanimous support. The bill is currently awaiting the President's signature. Due to recent gains in the areas of gene mapping and genetic testing, this legislation is of particular importance to the Alzheimer's community.

As we will hear today, genetic information plays an invaluable role in the early detection and treatment of Alzheimer's disease. The legislation we are talking about will protect the right of Americans to seek out genetic testing without fear that the results will be used against them either by an employer or an insurance provider. Our hope is that this protection will encourage broader utilization of testing methods and a greater chance of early intervention where possible.

Again, we would like to thank our witnesses for their participation in this hearing. To my knowledge, a congressional hearing has never cured a disease. But surely, with such a distinguished panel of witnesses, we can garner valuable ideas to raise awareness, anticipate challenges, encourage research, and support Alzheimer's patients as well as their families in the very best way that we can.

We now turn to the Ranking Member of this Committee, Senator Gordon Smith, for his comments.

OPENING STATEMENT OF SENATOR GORDON H. SMITH, RANKING MEMBER

Senator SMITH. Thank you, Mr. Chairman.

Ladies and gentlemen, good morning. This vast audience that has come here, I think, is a testament to just the kind of impact that Alzheimer's is having on America's families, and we thank you for your presence.

I particularly want to thank Justice O'Connor and Speaker Gingrich. It goes without saying that these are two historic Americans who are lending their great prestige to this issue that is so vital to healthcare in America and to our ongoing efforts to find a cure.

I want to particularly thank Charles "Chuck" Jackson, who is here in the front row. He will be testifying in the second panel. He has flown across the country from Albany, OR, to share his personal story of living with Alzheimer's disease. Whether it was through watching his family members suffer or in his personal battle, Alzheimer's disease has had a presence throughout most of his adult life.

In fact, Chuck, was diagnosed at age 50 with early onset Alzheimer's. He has lost 17 members of his family to the disease. I understand that Chuck's aunt, his Aunt Esther testified at one of the first hearings before Congress about the need to increase research funding. Chuck, we are pleased to have you here today, but it is unfortunate that we are continuing to have to hold hearings on this as the disease continues to proliferate, yet funding remains insufficient.

The instances of Alzheimer's disease in the United States are staggering. Every 71 seconds, someone in America develops Alzheimer's disease. An estimated 5.2 million Americans of all ages and 1 in 8 persons age 65 and older have the disease. Additionally, 10 million baby boomers can expect to develop Alzheimer's disease in the remaining parts of their lives.

In my State of Oregon, a total of 76,000 Oregonians have Alzheimer's disease or a related disorder. This represents a nearly 33 percent increase in the number of people age 65 and older with Alzheimer's disease over the last 8 years. Sadly, to date, there is no treatment to delay or stop the deterioration of brain cells in Alzheimer's disease.

To stem this tide, we must increase medical research funding for the NIH. Just 2 months ago, I sponsored an amendment to the budget to increase NIH funding by over $2 billion. Although this is a good start, we need to make sure that the funding actually gets appropriated. Across the Nation, many advances in research are being realized at NIH-funded facilities.

For example, in Oregon, the Layton Center for Aging and Alzheimer's Disease focuses on research aimed at detecting and preventing cognitive decline even before developing symptoms. The center integrates its activities with the Oregon Alzheimer's Disease Core Research Center, 1 of 30 national centers funded by the NIH.

In addition to supporting ongoing research, I am hopeful that Congress or the new administration, will lift the ban on Federal funding for embryonic research. This will allow our greatest minds in medicine to fully explore, in an ethical manner, the potential of these cells in creating Alzheimer's disease, as well as some of life's other devastating diseases, such as Parkinson's.

I also will continue to lead the effort here in the Senate to increase funding to the National Family Caregiver Support Program. This program is a component of the Older Americans Act, which funds an array of local programs to ensure that our seniors can remain in their homes as they age.

The caregiver program and the Older Americans Act is vital to ensuring that families can receive information and assistance about available services, individual counseling, respite care, and access to adult daycare or home care services. Funding for this program also works to organize support groups and establish caregiver training programs.

Unfortunately, all Older Americans Act programs are woefully underfunded, and the need for caregiver support far outweighs the support that local agencies are able to provide. I will continue to work with my partner on the Finance Committee in this effort, Senator Lincoln, to ensure that funding for these programs better reflects the needs of our country, and I ask that all of you help us in this effort with the Older Americans Act.

Fortunately, with the good work of the panel before us, as well as many others, families around the country are receiving help coping with the disease as well as finding treatment. I look forward to hearing from each of you about how Congress can better help support those individuals who are affected by Alzheimer's disease.

So, with that, Mr. Chairman, I turn it back to you.

The CHAIRMAN. Thank you, Senator Smith.

Senator WYDEN.

STATEMENT OF SENATOR RON WYDEN

Senator WYDEN. Mr. Chairman, thank you.

We have two very thoughtful guests, and I am going to be very brief this morning.

My mother got a master's degree from Yale back in the day when that was pretty much unheard of. Now she is on the second floor of Channing House in Palo Alto, a really wonderful facility, with a very advanced case of Alzheimer's and dementia. Justice O'Connor just mentioned to me a situation much like the O'Connor family is facing.

If my mother could speak today, she would probably say something like, "Well, Ronald, what are you going to do to help the others?" Today, I hope, will be the beginning of a national drive, literally a nationwide mobilization to forge a new strategy against Alzheimer's. The new strategy should be primarily about prevention. If there is one word that ought to capture our future strategy, that is it.

Because when you listen to Chuck Jackson—and we are so thrilled that you are here, Chuck—it is an inspiring story he tells about his effort to really ring the bell and generate national awareness about how important prevention is for those who are under 65.

So I am very much looking forward to our guests. I have had a chance to work with Speaker Gingrich often on healthcare issues. There is certainly nothing partisan about this one. Today, if we can do nothing else but drive home the importance of a new strategy that zeroes in on prevention, I think that is something that the whole country will rally to.

I thank you, Chairman Kohl and Senator Smith, for your leadership and bipartisan focus once again.

The CHAIRMAN. Thank you, Senator Wyden.

Senator Collins.

STATEMENT OF SENATOR SUSAN COLLINS

Senator COLLINS. Thank you. Thank you, Mr. Chairman.

I co-chair with Senator Hillary Clinton the Congressional Task Force on Alzheimer's Disease. So I am particularly pleased that you have called this hearing this morning so that we can get an update on where we stand in the battle against Alzheimer's.

I am, of course, delighted that we have Justice O'Connor and Speaker Gingrich with us. Both of them are members of the Alzheimer's Study Group, which is bringing together the most creative people that I can imagine to help us chart a new course in dealing with Alzheimer's.

As someone whose family has experienced the pain of Alzheimer's over and over again, I know there is no more helpless feeling than to watch the progression of this terrible disease. It is an agonizing experience to look into the eyes of a loved one only to receive a confused look in return. Of course, my family is by no means alone. An estimated 5.2 million Americans have Alzheimer's disease, including more than 25,000 people in Maine. That is more than double the number in 1980.

Moreover, Alzheimer's costs the United States about $150 billion a year. This figure is going to increase exponentially as the baby boom generation ages. Our investments in Alzheimer's research have begun to pay dividends. Effective treatments are tantalizingly within our grasp. Moreover, if scientists can find a way to delay the onset of this devastating disease for even 5 years, our Nation would save more than $60 billion every year in Medicare and Medicaid costs and an incalculable amount in human suffering.

So that is why it is so important that we make these investments, that we pursue every opportunity possible. This hearing helps set us in that direction.

So, thank you, Mr. Chairman. I am going to submit the rest of my statement for the record, and I appreciate your holding this hearing.

[The prepared statement of Senator Collins follows:]

PREPARED STATEMENT OF SENATOR SUSAN COLLINS

Mr. Chairman, as the Senate Co-Chair of the Congressional Task Force on Alzheimer's Disease, I am pleased that you have called this hearing to provide the Committee with an update on where we stand in the battle against Alzheimer's, and I want to thank Justice O'Connor and Speaker Gingrich for their advocacy. Both are members of the Alzheimer's Study Group.

As someone whose family has experienced the pain of Alzheimer's many times, I know that there is no more helpless feeling than to watch the progression of this dreadful disease. It is an agonizing experience to look into the eyes of a loved one only to receive a confused look in return.

My family is not along. An estimated 5.2 million Americans have Alzheimer's disease—including more than 25,000 people in Maine—more than double the number in 1980. Moreover, Alzheimer's costs the United States just under $150 billion a year, primarily in nursing home and other long term care costs. This figure will increase exponentially as the baby boom generation ages. As baby boomers move into the years of highest risk for Alzheimer's disease, a strong and sustained research effort is our best tool to slow the progression and prevent the onset of this heartbreaking disease.

Our investments in Alzheimer's research have begun to pay dividends. Effective treatments are tantalizing within our grasp. Moreover, if scientists can find a way to delay the onset of this devastating disease for even five years, our nation will save more than $60 billion every year in Medicare and Medicaid costs, and an incalculable amount in human suffering.

If we are to keep up the momentum we have established, however, we must increase our investment in Alzheimer's disease research. We have made tremendous progress, but this is no time to take our foot off the accelerator. That is why I am pleased to be an original cosponsor of the bipartisan "Alzheimer's Breakthrough Act" to double the authorization levels for Alzheimer's research at the National Institutes of Health.

In addition to increasing funding for research, we must also do more to support Alzheimer's patients and their families. I am therefore also pleased to be an original cosponsor of the "Alzheimer's Family Assistance Act" which will provide a tax credit of up to $3,000 to help families meet the costs of caring for a loved one with a long-term, chronic disease like Alzheimer's. The legislation will also encourage more Americans to plan for their future long-term care needs by providing a tax deduction to help them purchase long-term care insurance.

Alzheimer's disease is tragic at any age. But the tragedy is particularly poignant when it strikes early, disabling otherwise healthy individuals in the prime of their lives. Moreover, when Alzheimer's strikes before 65, it can create additional problems simply because it is so unexpected and because most of the potentially helpful programs and services are targeted to older people. I am therefore particularly pleased that this morning's hearing will also focus on the unique challenges faced by the growing population of "early onset" Alzheimer's patients who are diagnosed before the age 65.

Again, I want to thank the Chairman and the Ranking Member for organizing this important hearing which I hope will help us to identify new strategies that will move us forward in our battle against this terrible disease.

The CHAIRMAN. Thank you, Senator Collins.
Senator Salazar.

STATEMENT OF SENATOR KEN SALAZAR

Senator SALAZAR. Thank you very much, Chairman Kohl and Ranking Member Smith.

Let me just say to both Sandra Day O'Connor, a great justice, thank you so much for your service to our country for so many years and thank you for being here, and speaking out on such an important issue.

To Speaker Gingrich, thank you for your life beyond the speakership and for continuing to contribute to our country and dealing with major issues that face our time.

When I look at this audience that is here today putting a spotlight on the issue of Alzheimer's, I would imagine that almost everyone out there, including many members of this panel who are my colleagues in the Senate, have personal stories about Alzheimer's. Maybe it is those personal stories that make us all advocates for trying to deal with this issue.

Just like Senator Wyden's story with his mother, I, too, had a father, a World War II veteran who was strong as nails. There was nothing that could ever put him down. During the last few years of his life when he had Alzheimer's, keep his body was still strong and with the right kind of assistance he could still be out there feeding cows in his 80's, his mind was not there.

It is a very difficult and painful thing, I know, for all families to understand what happens with Alzheimer's, and it is important that we are doing what we are doing here today. Hopefully, it is just a mark in a journey that is going to be a long journey to get us to the point where we can actually prevent the disease.

Like Senator Wyden, I often wonder what my father would tell me today. He no longer is with us here today. But I think he would say, one, we need to get a much better understanding of the disease than we currently have.

I think when he first was coming down with Alzheimer's, we didn't know what was going on with him. There was a time period where he would act in ways that were just so strange, and no one had any understanding of why it is that sometimes he would want to choke someone within his own family on issues that had nothing at all to do with what the dialog was all about.

Then, second of all, moving forward in his life, watching his body still very strong, but his mind was no longer there was a very painful thing for all of us to go through. So I think enhancing the understanding of the disease among all Americans is something that is very important, and I also think that moving forward with the kinds of investments in research that we all support are very important for us to get a credible and effective prevention program.

Thank you very much, Senator Kohl and Senator Smith.

The CHAIRMAN. Thank you, Senator Salazar.
Senator Dole.

STATEMENT OF SENATOR ELIZABETH DOLE

Senator DOLE. Thank you, Mr. Chairman, and I certainly want to thank Ranking Member Smith for holding this hearing today. What a privilege it is to have Justice O'Connor and Speaker Gingrich with us today and other members of the panel that will follow.

As I look out across this hearing room and see the number of people here, I don't believe I have ever witnessed as many people at a hearing in the 5, 6 years that I have been in the U.S. Senate, which certainly speaks—yes. [Applause.]

I will be very brief because we want to hear from our witnesses. But as we are all aware, more than 5 million Americans are currently suffering from Alzheimer's disease, including more than 130,000 in my home State of North Carolina. There are about 300,000 caregivers in North Carolina, and if these caregivers were paid minimum wage for their time, it is estimated that the hours of care would be valued around $2.9 billion per year in North Carolina alone. It is incredible.

I am so pleased to have the opportunity to learn more today, to be a part of trying to find answers to these very serious problems. No question the need for more research is necessary to help prevent, diagnose, and treat Alzheimer's. It is tremendous the need here.

So just know that I am going to be a strong supporter. I am very pleased to be a part of the group that has a chance to learn this morning from our witnesses.

Thank you very much.

The CHAIRMAN. Thank you, Senator Dole.

Senator Carper.

STATEMENT OF SENATOR THOMAS CARPER

Senator CARPER. Thanks, Mr. Chairman.

To our first witnesses, Justice O'Connor, my former colleague Speaker Gingrich, welcome. We are delighted that you are here today, and thank you.

Thank you all for coming. Whether you are from Delaware or the other 49 States, we are glad you are all here.

My colleague Ken Salazar talked about his dad. My mom, who passed away about 3 years ago almost to the month from Alzheimer's disease, was—that was a picture I will telegraph, that her mom had had Alzheimer's disease. Her grandmother had had Alzheimer's disease as well. So we knew this was coming.

Even at the end, though, when I would visit her, among the things that we would do together, we would go to the chapel. There is a wonderful place that she stayed in Kentucky close to my sister and close to her younger sister, and we would read the Bible. It was really interesting. My mother was a deeply religious woman, and I would start off a Bible verse, and then she would finish it. She was really good at this.

I would sing, like start off singing a hymn, and she would finish it. Even near the end of her life, she was able to still do those things and provide the kind of connection that I hungered for and maybe she did as well.

Got a lot of people in Washington today. I think most of them are in this room, as Senator Dole said. But already today, I have

met with families from Delaware. I have met with students, groups of students from our State. I have met with a bunch of educators that are here from our State, doctors that are in town, and several lobbyists drifted by, and then all of you, all of you.

I just want to say that the most effective lobbyists that I have met here as a Senator, and as a Governor before that and Congressman before that, the most effective lobbyists I have ever met are the people from my State, from my own constituents, people that I know, people who know me.

I would just say to all of you, there is huge competition for these Federal research dollars. We doubled the NIH funding, I think, between 1998 and 2002. President Clinton said we are going to do it. President Bush in the first year or so of his administration helped to complete that pledge. It has been flat ever since. So much competition for Federal dollars.

I would just say you know the old saying, "The squeaky wheels get the grease?" Well, sometimes they do. A lot of times they do. I would just say that those of you that are here leaning on us, the rest of us to—when there is some extra money around, and we are facing a $400 billion budget deficit this year. But when there is some extra money around and we can wind down, for example, the cost of the wars that we are fighting these days and as we come out of the recession, that we make sure that some of those dollars are going to be allocated for the research that we need.

The last thing I will say, and someone else mentioned this, it is worth restating. For every hundred dollars or so that we spend in helping to keep our parents, our grandparents, our aunts and uncles in a nursing home and to take care of them the last months, years of their life, we spend one dollar, one dollar on research in trying to figure out how do we prevent this disease and how do we cure that. The sooner we can wake up to spend $2, $3, $4, $5 for the prevention and cure, we can spend a lot less of those $100 bills.

We need your help. Not just Federal dollars. Pharmaceutical companies spending money on this. The money that you and I raise on these Alzheimer's walks, the memory walks, all of it together will help us to get where we need to be.

Thank you very much.

The CHAIRMAN. Thank you, Senator Carper.

Senator Corker.

STATEMENT OF SENATOR BOB CORKER

Senator CORKER. Mr. Chairman, thank you for holding this hearing.

Out of respect for our distinguished witnesses, I will be very brief, but I do want to thank all those who are here.

Like everybody in this room, we have all been touched. On weekends in Tennessee, I visit my dad, who is strapped into a wheelchair to keep from hurting himself, and I just appreciate all of you bringing attention to this issue.

Thank you.

The CHAIRMAN. Thank you very much, Senator Corker.

We now turn to Senator Whitehouse.

STATEMENT OF SENATOR WHITEHOUSE

Senator WHITEHOUSE. Thank you, Chairman Kohl and Ranking Member Smith, for holding this hearing.

As we get closer and closer to the witnesses, the pressure on the panel to be brief grows and grows. So I will simply express my very great appreciation to Justice O'Connor for coming forward to bring the enormous reservoir of respect and affection that America holds for her to bear on this issue.

Speaker Gingrich, you have really distinguished yourself in your post Speaker years as somebody who has kept very, very much involved with these issues. Your co-chairmanship of the Alzheimer's Study Group with our former colleague Bob Kerrey, who I would like to recognize also, has really been a very important contribution, and it is inspiring to see this wonderful crowd.

So, thank you.

The CHAIRMAN. Thank you, Senator Whitehouse.

Senator Coleman.

STATEMENT OF SENATOR NORM COLEMAN

Senator COLEMAN. Thank you, Mr. Chairman.

I, too, shall be brief. Like my colleague Senator Corker, I have been touched personally.

I am just going to quote Machiavelli. A lot of philosophy is flawed, but he said this. "From knowing afar off the evils that are brewing are easily cured. But when for want of such knowledge they are allowed to grow until everyone can recognize them, then there is no longer any remedy to be found."

Let us take his advice and let this be the beginning of a national strategy to confront and cure this disease. [Applause.]

The CHAIRMAN. Thank you, Senator Coleman.

The Senator from Arkansas.

STATEMENT OF SENATOR BLANCHE LINCOLN

Senator LINCOLN. Thank you, Mr. Chairman.

It has all been said, but not everyone has said it. I, too, will try to be brief.

I want to say a special thanks to our Chairman, who always puts together incredibly thoughtful hearings. In the Aging Committee, it is an issue that is critically important to me and to my constituents in Arkansas, and I just want to thank him as well as our Ranking Member, Senator Smith, who I have worked with on the Older Americans Act and many of the things that we have been able to accomplish together.

But these two gentlemen do a tremendous job on this Aging Committee, where we bring forth so many different issues that are affecting the aging community in this country. Of course, all of us at some point will be aging. Without a doubt, those of us who grew up in communities and families where taking care of our aging family members was an honor and a privilege, it was something that taught us more about love and family than perhaps anything else that we may have learned in our lifetime.

I, too, like others, my dad was diagnosed with Alzheimer's at an early age. My siblings, my mother, we cared for him with a long journey of almost 10 years of suffering from Alzheimer's. Early on,

when it was something that was undiagnosable, we had him in the trials, different types of trials. But it was amazing not only to see him, but to see the caregivers, the people surrounding him all of his life.

He and my mother were high school sweethearts, and she never once gave up hope nor has she given up hope. She is still hosting house parties in our small community where visiting medical professionals come and talk to the community about the need for research and the need for the dollars and the new and exciting things that are coming out in research.

It has motivated me in many ways. The Chairman allowed us to have a hearing last year on the coordination of care and how important coordinating care for elderly, the elderly members of our family is and how incredibly economical it is to our medical dollars. But more importantly, how it is critically important to those who suffer from dementia and Alzheimer's.

So there are so many different things that we are all motivated by, but we are so grateful to be able to have this opportunity. There is no doubt for us here at the dais, for us to look out and see this crowd that is here, to understand the passion, the love, the interest that is in this room of how we find the kind of cures, the research that we need, how we need to even further our investigation of caregiving and what it does, what the needs are and what it does to our families, we are very grateful.

We are enormously grateful to our distinguished panel here. Justice O'Connor, thank you again for being here and all the many things that you have done in your service to this great country. Speaker Gingrich, thank you for your tremendous service as well. We appreciate both of you.

So, thank you, Mr. Chairman, for once again bringing us together in a remarkable way, as you always do in this Committee. Thank you.

The CHAIRMAN. Thank you, Senator Lincoln.

So we turn now to our first panel. Our first witness on this first panel will be Sandra Day O'Connor, our Nation's first female Supreme Court Justice. Justice O'Connor served 24 years on the Court. In 2007, she was nominated to serve on the Alzheimer's Study Group, a task force of national leaders charged with creating a strategic plan to address the growing Alzheimer's crisis.

She is currently the chancellor of the College of William and Mary. She also serves on the Board of Trustees of the National Constitution Center in Philadelphia.

Following her testimony, we will hear from Newt Gingrich. During his 20 years in Congress, Speaker Gingrich demonstrated his commitment to improving the American healthcare system, co-chairing the Republican Task Force on Health for 4 years prior to becoming Speaker of the House of Representatives.

Since retiring from Congress in 1999, Mr. Gingrich has continued to focus on healthcare issues. He co-chairs the National Commission for Quality Long-Term Care, and he is also a member of the Alzheimer's Study Group.

Justice O'Connor.

STATEMENT OF HONORABLE SANDRA DAY O'CONNOR, FORMER SUPREME COURT JUSTICE, MEMBER OF THE ALZHEIMER'S STUDY GROUP, WASHINGTON, DC

Justice O'CONNOR. Mr. Chairman, thank you for—and all the members of the Committee, thank you so much for having the hearing and for inviting us to share a few minutes with you this morning.

I think the members of this Committee are probably more knowledgeable than any of us about this disease. You have exhibited from your statements already a depth of knowledge and understanding about the problem that tells me you are not going to learn anything new from us today.

But Speaker Gingrich and I are both serving on this study group, which we hope within the span of a year to be able to come back with some recommendations. I am sure that as members of the Committee interested in it, you will have heard many of the recommendations already, but perhaps we can shed some further light on it.

But I am here in the position of being a caregiver. My beloved husband, John, suffers from Alzheimer's. He has had it for a long time now. He is not in very good shape at present.

So, I have some appreciation for the depth of feeling that you have that has generated the interest and the people who are in this room today. Do magnify that by people in every State of this country, and you will understand the depth of concern that is out there.

This is a really difficult disease because it has no cure as yet. You have done work by funding research in this area and by considering some laws, I congratulate you on the one you just passed to enable people to get an early diagnosis and not thereby forfeit the right to get long-term care insurance. That is really important. I congratulate you on addressing that problem and doing something about it. That should help.

My own sons have not wanted to go be tested, even though, obviously, with their father in the condition he is, they should know. But out of the fear that they would then be ineligible for insurance they have not done so. So you have done a wonderful thing in getting that legislation passed.

Researchers really haven't clearly determined yet why some of us get Alzheimer's and others do not. We don't totally understand the biological processes that cause these devastating effects, but researchers are closer today than ever before in developing some proposed drug treatments that might dissolve the amyloid plaque in the brain. But that is going to require serious clinical testing. If you are going to dissolve something in the brain, you want to be sure it isn't the brain itself.

So that is why the studies are lengthy, to make it something that we can trust to use. But if you can just shave off by 5 years the onset of Alzheimer's, broadly speaking, think of the money you would save nationally on healthcare. I mean, it is just incredible. So everything you are doing is worth the effort. It does take a staggering toll on the families and the caregivers. I can certainly attest to that.

Now I don't know what the official thinking is on the expansion of Alzheimer's in the future, but the doctors who take care of my

husband tell me that one in two people over 80 are going to have Alzheimer's. Now I am getting pretty close to 80. So that gets my attention. I think a lot of people will be concerned when they look at it from that standpoint.

What we have to ask is whether this rapid growth is inevitable. I think it is not if we can fund the research and encourage it and enable testing to be done and get clinical trials coordinated and broadly based so that maybe they don't have to go on forever. We might even encourage drug companies to do more if they thought that they could somehow extend the life of the patent.

I mean, it could take 15 years to do the testing. If the patent life is 17 years, you are not going to have a lot of encouragement there for this kind of thing. So I think the Committee has a need for considering coordinated approaches to what we need to do because this is a problem that cries out for help, and we do need additional research.

We need to continue to teach people how to care for Alzheimer's patients. It is better if they can stay home, but they reach a point where often they can't. Daycare is helpful at earlier stages of the Alzheimer's patient, very helpful. So, how can we do that?

I think that our Nation is certainly ready to get deadly serious about this deadly disease, and I think that your approach here in the Committee and in Congress encourages me to think that you are quite well informed and quite interested in doing something about it.

I think we have to expand the research efforts, and we have to encourage the sharing of research data across the country with those who can help further this process. I hope that we can encourage the private investment that it is going to take to make drugs, treatment drugs in this area widely available to the public. We certainly need to encourage the support systems that we have for the families and the patients themselves.

I just thank you for focusing on this and for sharing with each other and with everyone in this room your own personal experiences with it. They are heart-rending, as everybody in this room can tell you.

Thanks.

[The prepared statement of Justice O'Connor follows:]

Statement of
Sandra Day O'Connor
Retired Associate Justice
U.S. Supreme Court

Before the
Special Committee on Aging
United States Senate

May 14, 2008

Chairman Kohl, Ranking Member Smith and members of the Committee. I appreciate the invitation to testify before you today. I commend you for delving into a subject that is very dear to my heart and to the hearts of the millions of American families who love and provide care to relatives who have Alzheimer's disease.

As you know, I became one of these caregivers in 1990 when my husband, John, was diagnosed with Alzheimer's. Living with this disease has been sad and difficult for my entire family. But it has also given us a first-hand understanding and a profound empathy for caregiving families around the nation. These caregivers are continually called upon to make fundamental sacrifices and adjustments in their lives in order to nurture and support the people they love.

You may remember that in the early days of my husband's illness, I often took him to court with me because he could not be left alone. And, as you know, I retired from the U.S. Supreme Court in 2006 to find a care center for John in Phoenix, where two of our children live. Many caregivers make similarly difficult decisions each and every day. Sadly, these life-changing decisions are simply part of caring for someone with Alzheimer's.

Clearly, Alzheimer's disease is a family disease. It may directly attack only one member of a family. But every member of that family feels the effects. Every member loses something.

Alzheimer's ruthlessly robs families of husbands and wives, mothers and fathers, grandmothers and grandfathers, aunts and uncles, brothers and sisters. Researchers are now telling us that the disease can also rob caregivers of their health. According to a recent study in the *Journal of Immunology,* people who care for relatives with Alzheimer's are twice as likely as non-caregivers to suffer from depression. They are also more likely to develop a compromised immune system that could shorten their lives.[1]

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[1] Damjanovic, A.K., Yang, Y., Glaser, R., Kiecolt-Glaser, J.K., Nguyen, H., Laskowski, B., Zou, Y., Beversdorf, D.Q., Weng, N.P. 2007. "Accelerated telomere erosion is associated with declining immune function in caregivers of Alzheimer's disease patients." *Journal of Immunology*, 179: 4249 - 424.

Researchers have not yet determined why some of us develop Alzheimer's and others do not. We do not yet fully understand the biological processes that cause such dramatic degeneration. But families with Alzheimer's know all too well the devastating effects.

From even the earliest stages, the symptoms of Alzheimer's disease are very difficult to handle. As the disease progresses—often over the course of decades—its symptoms become cruel and punishing. This disease begins quietly, with memory difficulties that gradually become more serious and much more frightening with each passing year. Then, what follows is confusion ... impaired judgment ... trouble expressing even the simplest thoughts ... disorientation ... and socially inappropriate behavior.

Eventually, formerly self-reliant, articulate and loving family members lose the ability to bathe, dress or eat without help ... lose the ability to communicate ... and fail to recognize the spouse or the children for whom they have cared so deeply for so many years. I submit to you that until you have actually stared Alzheimer's in the face, as millions of Americans and their families have done, you cannot truly understand the deep sense of frustration, fear, helplessness and grief that accompany it.

While Alzheimer's takes a staggering toll on families, it is not *just* a family disease. Indeed, Alzheimer's is fast becoming a national disease – a national health crisis.

The Alzheimer's Association estimates that 5.2 million Americans now have Alzheimer's disease—a figure about equal to the population of Wisconsin. More than eight million Americans over the age of 65 could have the disease by 2030—that's roughly the combined populations of Wisconsin and Oregon.

Alzheimer's also brings with it a staggering cost. The nation now spends an estimated $150 billion each year to care for people with Alzheimer's. The disease's enormous budget impact will only grow larger by 2050, when as many as 16 million Americans could find themselves in its grip.[2]

Is this rapid growth in Alzheimer's cases inevitable? I do not believe it is. That is why I am here today and why I chose to join the Alzheimer's Study Group. As you know, the Alzheimer's Study Group is a taskforce of national leaders charged with creating a National Strategic Plan to overcome the mounting Alzheimer's crisis. This group has received bipartisan support here on Capitol Hill, and rightly so. It represents an important step in helping the United States establish and carry out a bold national goal – one that seeks nothing less than to eradicate Alzheimer's disease.

Our collective experience with Alzheimer's to date – as family members, scientists, medical professionals and policymakers – has convinced group members of three critical facts.

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[2] Alzheimer's Association. 2008. *Alzheimer's Disease Facts and Figures 2008.* Retrieved from Alzheimer's Association, May 7, 2008. Web site: http://www.alz.org/national/documents/report_alzfactsfigures2008.pdf

- ***First***, Alzheimer's is a complicated disease that requires a coordinated, multidisciplinary response. We need to fight this killer not only in the research lab, but also at the treatment site, in the halls of government, and in the communities that people with Alzheimer's call home.

- ***Second***, we will never succeed in tackling Alzheimer's by tweaking our existing systems or being satisfied with piecemeal, incremental changes. Instead, we must transform our thinking about Alzheimer's. We need to create new research, treatment, care and support systems. And we need to make sure that those systems work together toward common goals.

- ***Third***, we need to move quickly. I cannot over-emphasize the need for urgency. The families of people with Alzheimer's disease are impatient for new treatment options that can offer new hope to them and their loved ones. We must resolve, by our swift action, that the current generation of people with Alzheimer's will be the last generation that we lose to this miserable disease.

A forward-thinking nation, led by a forward-thinking Congress, can take steps now to transform our approach to Alzheimer's. Specifically:

- We must expand clinical and research efforts that improve the diagnosis and treatment of Alzheimer's disease. In particular, we must aggressively emphasize prevention and early diagnosis. Researchers increasingly agree that, just as with heart disease, early intervention offers the best opportunity to stop Alzheimer's in its tracks. By taking swift action we can spare millions of Americans from the indignities of Alzheimer's.

- We must encourage researchers to share their insights with one another in real time—rather than waiting many months, or even years, until patents are filed or study results are published. As a nation, we are depending on these gifted experts to deliver the breakthroughs we need so desperately. In return, we need to support their work fully by offering them new opportunities and incentives to work together on a much broader and more collaborative scale.

- We must renew our commitment to strong public investment in developing new treatments. We have been far too lax on this front. Despite the growing number of Alzheimer's cases, public funding for Alzheimer's has grown very little in the past 5 years. In fact, when biomedical inflation is taken into account, funding levels have actually declined.

- We must also encourage the sustained private investment that will help translate research breakthroughs into new treatments. Disturbingly, we see signs that the private sector is losing interest in funding Alzheimer's programs because of the scientific challenges, the regulatory uncertainties and delays, the reduction in effective patent life for preventive therapies, and unclear reimbursement policies.

- Finally, we must improve formal and informal supports for those who currently have Alzheimer's and for their caregivers. It is time to ensure that ***best*** practices in Alzheimer's care become ***standard*** practices in communities across the country.

The Alzheimer's Study Group is working closely with experts from around the country to develop strategies that address these and other issues. Our group includes leading experts in the fields of medicine, research, policy, education, communications, business and law. This multidisciplinary approach makes the Alzheimer's Study Group unique and, I believe, gives it a much greater chance of success.

Thank you for allowing me the opportunity to speak as one of the millions of family members around the country who are caring for people with Alzheimer's disease. I suspect that you will not hear from many of my fellow caregivers directly ... not because they are uninterested in the topics I've raised, but simply because they do not have the resources to take time away from their loved ones in order to come before you. I am truly honored to represent these courageous Americans here today.

In closing, let me challenge you, as representatives of these same Americans, to address this growing national Alzheimer's crisis with the urgency it demands. When the Alzheimer's Study Group releases its final report early next year, I ask you to carefully consider our recommendations. Keep these families in mind when you choose how to act on those recommendations. The stakes are high. Without a doubt, the future health and well-being of these families – indeed, the health and financial well-being of our entire nation – depends on how swiftly and decisively we act to address this terrible disease.

The CHAIRMAN. Thank you very much, Justice O'Connor. [Applause.]

Speaker Gingrich.

STATEMENT OF HONORABLE NEWT GINGRICH, FORMER SPEAKER OF THE HOUSE OF REPRESENTATIVES, MEMBER OF THE ALZHEIMER'S STUDY GROUP, WASHINGTON, DC

Mr. GINGRICH. I am going to say, first of all, it is a little intimidating to follow Justice O'Connor, who I think communicated powerfully the emotional and moral case.

I do want to thank Senator Kohl and Senator Smith for hosting this and allowing us to come here.

I have submitted testimony for the record and ask that it be accepted as such. I would like to summarize.

I also want to thank Senator Collins, who, along with Senator Mikulski, Burr, and Clinton, helped us launch the Alzheimer's Study Group, when Senator Kerrey and I were up here about 8 months ago.

I feel very honored—Senator Kerrey and I had co-chaired a Quality of Long-Term Care Commission for about 3 years, and it became obvious that if you are really going to deal with long-term care in America, you had to focus intensely on Alzheimer's. It meant a great deal to us to have Justice O'Connor join us in the Alzheimer's Study Group.

Just briefly let me list Dr. Christine Cassel, the geriatrician and president of the American Board of Internal Medicine. Meryl Comer, who is president of the Geoffrey Beene Foundation Alzheimer's Initiative and who herself is a remarkably powerful witness to being a family member coping with Alzheimer's, and she is here today.

Dr. Steve Hyman, the provost at Harvard. Henry McCance, who is chairman of Greylock Partners. Dr. Mark McClellan, who is the director of the Engelberg Center for Healthcare Reform at the Brookings Institution, was the head of the FDA and the head of the Center for Medicare and Medicaid Services.

James Runde, who is special advisor to Morgan Stanley. Dr. David Satcher at Morehouse Medical School, who was the head of the Centers for Disease Control and the former Surgeon General of the U.S., and Dr. Harold Varmus of Sloan-Kettering, who is the former head of NIH, form the Alzheimer's Study Group.

So we have tried to assemble a team that really brings a unique level of expertise, and I am going to try to broadly represent their thinking and add a few points in my summary.

I also want to thank the Alzheimer's Association leadership. Their 2008 Alzheimer's Disease Facts and Figures is as useful an introduction to this and as authoritative as there is in the country, and they do an extraordinary job of pulling together people who have a deep concern about Alzheimer's.

I want to thank George Vradenburg, who has been particularly helpful in coaching Rob Egge, who is the staff director of the Alzheimer's Study Group, and myself in working on this.

You have already mentioned the impact of Alzheimer's again and again, and I recommend to all of you, if you have a chance, to see Meryl Comer's video, which is very powerful. My sister-in-law's

mother currently has Alzheimer's. I think a number of you, as well as Justice O'Connor, have outlined the personal human challenge and the pain for the family.

Many years ago, I called Nancy Reagan one evening, and she said it is such a cruel disease because you are dealing with a person who in every way looks like the person you used to know and yet in so many ways they have changed. I think that captured the sense of cruelty and difficulty.

Yet there is enormous hope for a better future, and the Alzheimer's Study Group has established five areas—it is in the testimony—encouraging collaboration among researchers, improving Alzheimer's clinical trials, rapid learning from large electronic health datasets, integrating a community-based care model, and providing better information to policymakers.

I think if we look at the possibilities, I want to start with a broad generalization. I would really encourage the entire Congress and the executive branch to take this much more seriously than we do. We are going to have four to seven times as much new science in the next quarter century as we had in the last quarter century. Sixty-five percent of it will come from outside the United States.

No one on the planet understands how you cope with this flood of new information. Research on the brain will be one of the most extraordinary areas of explosive new knowledge because it is the most complex area of science, and we have only had really decent technologies for the last 15 years. Almost all of them, by the way, came out of the National Science Foundation investment, not the National Institutes of Health.

It is physics and math, which is the underlying base of the tools, which allow researchers into the brain to acquire real-time data about living brains. So, it is very important to understand that a truly basic research strategy has to involve the National Science Foundation as well as the National Institutes of Health.

If you take seriously what I just said, and I would be glad to answer the question of how we got to the four to seven number, it is inconceivable that we know today as policymakers what is possible. If we get four times as much new science, then trying to think out to 2033, which is not very far away if you are thinking about something like Alzheimer's—I mean, you look around this room and look at the number of people who are likely to be alive in 2033 and look at the number who are likely to be entering precisely the age that Justice O'Connor talked about. All of a sudden, this gets to be very personal for most of the people in this room.

But if you are looking out to 2033 and we get four times as much new science, you are the equivalent of a Senate committee in 1880 trying to understand today. 1880 is pre-automobile, pre-airplane, pre-radio, pre-motion picture, pre-long distance telephone, pre-electric light. I mean, how would you explain to a Senate committee of 1880 how you got to work this week or how you go back home to your State or how you stay in touch or the BlackBerry in your pocket or the cell phone with a camera?

Yet no one tries to say if we could have breakthroughs on that scale, what is our investment strategy? If I had one really powerful thing I would like to get you to focus on it is to take head on the

Office of Management and Budget, Congressional Budget Office design.

I was startled. About 4 years ago, I was trying to understand what we were doing wrong in the global war on terror and on Iraq. I met with Fred Smith of FedEx to talk about our lack of metrics and our lack of ability to manage large systems.

At one point in our breakfast, he said Government cannot distinguish between investment and cost. Therefore, Government could never tolerate in building FedEx or UPS because you could never explain why the wireless and the laptop are so central.

Now I will say to you as an aside, as an illustration, if I might? The recent decisions by the Census Bureau are so out of touch with modern reality they verge on insanity, and yet nobody is standing up and saying, "Let me get this straight. In the age of eBay, YouTube, Facebook, MySpace, Google, we are going to hire 600,000 temporary workers to do a paper and pencil census in 2010?" Which would be grounds, I would argue, for replacing the entire department and just saying anybody dumb enough to believe in this is so out of touch.

But let me suggest to you, when you look at Alzheimer's, we have current projections of a $1.2 trillion in Federal spending for the baby boom generation, matched by a $1.2 trillion in personal spending. Now if you instructed the Congressional Budget Office to design a generational investment strategy because you know what is going to happen, we are going to run out of money. We are going to nickel and dime truly stupid things to try to save money in Medicare and Medicaid. When if you started right now and had an investment strategy, you might postpone Alzheimer's by 5 years. If you postpone Alzheimer's by 5 years, you save half that money, $600 billion.

Now if you go to say what is the time value of money, and could we set up a brand new—an amendment to the Budget Act for an investment strategy that is fundamentally off budget, but manageable and defined and that counts against future savings? This applies to many diseases, but in particular, since we are here today talking about Alzheimer's, it applies massively to Alzheimer's.

Now let me carry it a stage further. We have to look at, first of all, how do you accelerate basic research in the world I am describing? I think that means—and I say this having helped double the NIH budget while we were balancing the budget. So when people tell me we don't have enough money, we have about $3 trillion. It is a question of priorities. I would argue passionately NIH should grow at 7 percent a year in constant dollars. That is about the amount you need annually in order to sustain the momentum of research.

Second, I would triple the NSF as rapidly as possible. The biggest single mistake I made as Speaker was not tripling the National Science Foundation, which was a much smaller institution, while doubling the NIH. As a result, we are not getting the investment in math, physics, and chemistry we need and in basic nonhuman biology, all of which are central to our future.

I would also insist that Government research have a substantial information technology investment, and I would insist on fundamental set-asides for young researchers. We are moving into a

cycle right now where we are over investing in old senior researchers who have great prestige, but no new ideas. This will get me in a lot of trouble with NIH. [Laughter.]

But the truth is—the truth is in an age of radical scientific change, you want to consciously allocate a fair amount of money to people under 40. You don't want anyone to have to spend half their lifetime working as an apprentice to somebody who is wrong. Again, just read Kuhn's "The Structure of Scientific Revolutions," and you will get some sense of the scale of change that I am describing.

We also want to focus on translating basic research into applied research. I think that means make the R&D tax credit permanent. I think this will be fairly controversial. I think you should review the ethics rules to make sure we have not created such solid firewalls at NIH that we, in fact, inhibit the flow of knowledge back and forth.

The great engines of translating research into productive use are the private sector engines. If we build walls that are too strong, we, in fact, inhibit the transfer of knowledge in a way that is very, very dangerous in the long run.

How do we accelerate translating applied research into usable medications? I think that requires FDA reform. I think that—and particularly in the area of brain science because a lot of the rules that make perfect sense if you are looking at a normal physical behavior, cancer or whatever, don't make sense when you are dealing with the brain. I think that you need a fundamental rethinking of how the FDA deals with research and breakthrough in the brain.

How do we get the new breakthroughs used on a daily basis? Remember that, excuse me, the National Institute of Medicine points out that it takes up to 17 years to adopt a new best practice. I would encourage the National Library of Medicine to help create an electronic Internet-based, real-time 24/7 learning system for doctors and recognize that the continuing medical education has to be permanent. It has to permeate the system, and it has to be real time.

I would look at very fundamental investment at the National Library of Medicine to develop that kind of capability because you want to get the newest breakthrough to your mother's doctor this week, not in 17 years.

I think you have to encourage the pharmaceutical investment in brain science and in the whole range of brain diseases. I would strongly encourage you to amend the Orphan Drug Act to include all brain research as an orphan drug activity. That would begin—because this is a zone that is very complicated and very hard, and as a result, pharmaceutical companies aren't going to invest in it.

If you want to maximize the private sector investment, you want to maximize the possibility of real return. If all of the work done on Alzheimer's and on Parkinson's and other brain conditions was treated as an orphan drug for patent purposes, you would dramatically explode the amount of money being spent.

Now I understand the countervailing argument, which is that means you have the drug on patent longer. But let me just suggest to you having the drug is precedent to being able to get it to be generic. If nobody is going to do the research to ever develop the drug, you are never going to get to the generic.

I would rather spend a few extra years on patent and actually have the drug to save lives than have it explained to me why we blocked them from having it on patent because that taught them, but, by the way, the drug doesn't exist. It is a very fundamental policy question about how we accelerate private sector investment in this kind of an area.

I would also suggest to you three final very large changes. The first I have already mentioned. If you can move to an investment strategy on a generational basis, you can justify a dramatic increase in investment in these areas, and you will, over a decade to 15 years, get an amazing level of payout that will save the budget an extraordinary amount of money.

Second, you should create a public/private partnership for developing the use of electronic health data. We have over 40 million electronic health records today. They can be used on a depersonalized, anonymous basis with all HIPAA protections that are necessary. But do not bury this at NIH.

This is the kind of thing where you all ought to have a hearing, and you ought to bring in the head of eBay and the head of Google and the head of YouTube and the head of Facebook and people of that caliber and say to them, what would a public/private partnership look like that allowed us to use the best of IT to create an electronic epidemiology that allowed us to track millions of data points in real time in a way that we have—?

Remember, the Framingham study is a very small number of people, and yet it is the most famous single cardiology study ever done. We have literally at the Veterans Administration, at Kaiser Permanente, and at a dozen other facilities, we now have enough medical records over enough years that if we had a serious investment in electronic epidemiology, we would have an extraordinary amount of new knowledge about what works, what doesn't work, what are the various patterns. Nobody has seriously explored this yet.

None of the research systems are using the potential we have, but I would consciously not allow that to be purely an NIH function.

Last, with as much money as Alzheimer's is going to cost in as many different places, I would really urge you to create a White House coordinator who has reach across the entire Federal Government. It is an absurdity to have all the different pockets of funding—well, the same thing would apply to diabetes and one or two other large disease centers.

We have these huge, very expensive—these are things that cost more than any department in the Federal Government, except HHS and Defense. Yet they are totally uncoordinated, and there is no capacity to bring people together and force them to talk to each other and try to get these things done in a way that makes sense.

I would really look at a matrix management model for this kind of thing and try to have a coordinator who had reach into every aspect of Federal spending on this kind of area. So you could begin to think about what are the five problems I most wish I could solve this year, and where can I make the investment to solve them? That is today not done anywhere in the Federal Government in an effective way.

Anyway, I appreciate you giving us this kind of opportunity. I hope that between us, with the power and the prestige that Justice O'Connor can bring and with the work that the Alzheimer's Study Group is doing, I hope that we can work with you over the next few years and truly make dramatic breakthroughs in enabling America to have a dramatically better future in the area of Alzheimer's.

[The prepared statement of Mr. Gingrich follows:]

Statement of
Newt Gingrich
Former Speaker of the House
U.S. House of Representatives

Before the
Special Committee on Aging
United States Senate

May 14, 2008

Chairman Kohl, Ranking Member Smith and members of the Committee. Thank you for this opportunity to discuss the growing crisis that Alzheimer's poses to our Nation, and what we can do to accelerate and revitalize our efforts against this terrible disease.

Over the past several years I have steadily increased the time and energy that I have devoted to Alzheimer's, and I have been drawn to do so from several perspectives. This growing focus culminated this past year in my decision to organize a taskforce of national leaders to wrestle with this challenge. I co-chair this taskforce, the Alzheimer's Study Group, with former U.S. Senator Bob Kerrey. I speak to you this morning in that capacity. The Study Group is a remarkable and diverse group of national leaders – leaders such as Justice O'Connor whom I am honored to testify with this morning.

The Alzheimer's Study Group was convened to develop a National Alzheimer's Strategic Plan. We are developing the recommendations in this plan through a focus on five key objectives:

- Encouraging collaboration among researchers;
- Improving Alzheimer's clinical trials;
- 'Rapid learning' from large electronic health datasets;
- Integrating a community-based care model; and,
- Providing better information to policymakers.

I will have more to say about these strategic objectives later in my testimony.

Each of us on the Alzheimer's Study Group no doubt has our own reasons for agreeing to devote a substantial portion of this coming year to grappling with the challenges posed by this disease. But I do believe we hold several reasons in common.

First, the members of the Study Group share a conviction that Alzheimer's is a truly large and momentous challenge to our Nation. We must act now, or we will pay a far, far greater price in the decades ahead.

Second, we share a sense of tempered optimism that America can rise to meet this challenge. America has done so for other diseases; it will not be easy, but we certainly can do so with Alzheimer's as well.

Third, like most every American of our generation, Alzheimer's is simply part of our lives. Some members of the Study Group currently care for loved ones with Alzheimer's. All of us have witnessed its impact on friends, colleagues and relatives. None of this makes us exceptional. Rather, in this respect we are all too typical. Sooner or later, it hits all of us.

I've faced the particular cruelty of this disease at various times over the years. I first encountered Alzheimer's in my 30's when I taught the men's bible study at First Baptist Church in Carrollton, Georgia. I watched with both frustration and sadness as the disease claimed one of my good friends.

Years later, talking with Nancy Reagan during the long process of President Reagan's illness further convinced me that we had a moral obligation to focus on this terrible disease.

Meeting people with Alzheimer's living with my mother at the Homeland Center in Harrisburg, Pennsylvania, over the last years of her life convinced me that most of us live oblivious to its impact on individuals, their families, and our institutions.

At the Center for Health Transformation and through my work as co-chair, also with Senator Bob Kerrey of the National Commission for Quality Long Term Care, it became obvious to me that we could never deal with the fiscal crisis of long term care without substantially improving our capability to treat Alzheimer's successfully.

And now, in my own family, I have watched my sister-in-law care for her mother as she is slowly but irretrievably claimed by the disease.

Most everyone I speak with of my generation can recite a similar list of experiences. Alzheimer's is steadily becoming the uneasily discussed – and often preferably ignored – touchstone of the baby boom generation.

A Crisis Born of Success

In a sense, the Alzheimer's disease crisis is a product of success. Over the past century, clinical and public health advances have added more than 30 years to the average American's life. All of us can anticipate living substantially longer than Americans of prior generations.

But this success, together with the aging of the baby boom generation, means that the number of those with Alzheimer's – already far too high – will increase substantially in the years ahead. The odds of developing Alzheimer's double every five years after 65. It strikes 1-in-8 Americans over age 65 and almost half of Americans over 85. And so Alzheimer's is even now draining this success of its meaning as it robs millions of Americans of their memories, and then their minds.

We now know that just as decades of plaque accumulation and arterial hardening precede heart disease, a decades-long cerebral assault precedes the first recognizable manifestation of Alzheimer's. Many in this room today are even now losing a silent battle against Alzheimer's steady, unrelenting attack – though symptoms of this lost struggle may not appear for years to come.

So far, we don't have any way to block this decades-long descent into Alzheimer's. You will never meet an Alzheimer's survivor – there are none. Alzheimer's always ends in death. Perhaps that's why older Americans fear it more than cancer, heart disease, or any other disease.

Personal Loss; A National Crisis

Alzheimer's is also all too predictable on a national level. More than 5 million Americans currently suffer from this brain-destroying disease. With the aging of U.S. baby boomers, the Alzheimer's Association recently estimated that fully 10 million from my generation will develop the disease in the years ahead.

What's more, because Alzheimer's robs capabilities and independence it's also very expensive. This year the Federal government will spend more than $150 billion to care for those struggling with the disease. If we did not rely on family caregivers to bear so much of the burden, this figure would be far higher still.

Even so, the government's annual $150 billion liability is only a foretaste of what awaits our Nation. Under current trends Federal spending on Alzheimer's will increase to more than $1 trillion *per year* by 2050 in today's dollars. That's more than one tenth of America's current economy. With this amount of money at stake, the government simply will not be able to solve its looming fiscal problems if it fails to address the growing Alzheimer's crisis.

And yet, for all this, as I mentioned earlier there is solid ground for hope. The same impressive pace of innovation that has allowed us to live longer and make substantial progress against so many other diseases may help us defeat Alzheimer's as well. Researchers in academia and industry are steadily unlocking the mysteries of various aspects of the disease. Our great challenge now is to assemble this steady procession of insights from labs and clinics around the country into treatments that will upend these grim projections.

It's important to note that we don't even need to discover the Holy Grail – The Cure – to substantially blunt Alzheimer's future toll. According to a Lewin Group analysis commissioned by the Alzheimer's Association, a research advance that delayed the onset of Alzheimer's by just five years would translate by 2050 into a 5.3 million person (40%) reduction in disease prevalence and roughly $515 billion (44%) in annual savings for the Centers for Medicare and Medicaid Services (CMS).

A Lesson from the World that Works: Start with a Strategy

So, are we doing all that we can to speed such breakthroughs and to bring some measure of relief to families already contending with this disease?

The sad but undeniable fact is that we have been entirely too complacent in the face of this growing crisis. Nowhere is this clearer than within the Federal government itself.

You might expect me to back that charge with a critique of the current National strategy. But that's just the point. There is no National strategy. It doesn't exist.

To be sure, there are strategic Alzheimer's plans within some of our health agencies and institutes. In fact, some of these plans contain very thoughtful and promises strategies – strategies that have yielded world-class programs like the Alzheimer's Disease Neuroimaging Initiative (ADNI).

What's missing, however, is critical: an overarching strategy for the Federal government as a whole. There is no strategy that articulates Washington's overarching goals, objectives, strategies and metrics, or that serves to coordinate and maximize the sum of the activities underway across all the various Federal agencies.

Do we really need such an overarching strategy? Or would that just be a triumph of process over practice; a distraction from the work that needs to be done, and little more?

To answer that question first consider that, taken on its own, the $150 billion that the US federal government will spend this year on Alzheimer's would place it among the ten largest corporations in America. That's the scale and complexity we are talking about here – a Fortune 10 company.

Now, if you were to ask the CEO of any of those ten largest US companies to describe how important a clear, coherent, carefully implemented strategy is to their success, he would tell you that such strategic planning is essential. On what grounds do we assume that a clear, organizing strategy is any less important for our nation's battle against Alzheimer's? After all, not only are similar dollars at stake but – much more importantly – millions of lives hang in the balance as well.

Some would likely object that our government simply can't afford to craft an individual strategy for a specific disease. Instead, they would say, we should just let the National Institutes of Health (NIH), the Food & Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC) and other agencies do their own thing. That's the conventional wisdom in Washington. But that thinking would be met with astonishment in the board rooms of our Nation's best run organizations.

Imagine, for instance, if Richard Wagoner, the CEO of General Motors, announced that GM will no longer develop distinct strategic plans for its pickups, sports cars, luxury vehicles, or sub-compacts. No need for distinct strategies; after all, they are all vehicles.

Imagine, further, that Mr. Wagoner announced instead that GM will just let its individual operating divisions – manufacturing, finance, marketing and so on – make their own decisions regarding each car model without coordinating with any of the other divisions.

Clearly that example is absurd – almost too absurd to imagine. But someone from the Federal government needs to explain to this committee why it is any less absurd for the Federal government to assume that there is no need for a distinct federal strategy for Alzheimer's or to not insist on careful coordination among the various Federal health agencies.

By contrast, consider the intellectual energy and time that the leadership of America's best run public and private organizations put into strategic planning and execution. Is this wasted effort? A triumph of process over practice? Consider how much effort executives at leading companies like Fed Ex, GM or Microsoft devote to analyzing, planning, and monitoring to ensure figures much smaller than $150 billion are spent with maximum effect – so that waste is minimized and benefits are maximized. This is how our Nation's most successful organizations approach issues of this magnitude. They sweat over it.

The Signs and Consequences of Strategic Drift

So if this is right, we should be able to point to how this lack of a strategy is leading to bad outcomes. In fact, that's exactly what we can do.

Take the example of our Federal investment in the search for disease-modifying treatments. For every dollar the Federal government now spends through Medicare and Medicaid to care for those with Alzheimer's, it invests *less than a penny* to accelerate the discovery and development of effective therapies through the work of NIH and FDA.

This penny-on-the-dollar approach toward Alzheimer's is about as good an illustration of a "penny wise, pound foolish" policy as one could imagine. The government under-invests in accelerating the search for effective therapies based on the argument that there's simply no more money. They ask, how can we afford to do more?

However, each day we go without such treatments leads the government to spend many, many times more than the total devoted to Alzheimer's at NIH and FDA in order to cope, as best it can, with Alzheimer's devastating impact. A strategic perspective on such imbalances would immediately lead us to the right question: How can we afford *not* to do more?

Because we have framed this issue without a strategic reference, the investment gap grows wider each year. Federal funding for Alzheimer's research has remained flat for years – declining, in fact, when accounting for inflation. All the while, the cost of caring for those with Alzheimer's increases.

Consider another example: the Administration on Aging's Alzheimer's Disease State Matching Grants program. The intent of the program is to support state innovations to enhance care for individuals with Alzheimer's and their families, especially in minority, low-income and rural communities. For several consecutive years, the Bush administration's budget has proposed eliminating the program's funding. And in each of these years, as it has since 1992, Congress has acted to keep its funding intact.

Should this program be funded? Perhaps the Administration has a compelling case for canceling the program. But making a convincing, thoughtful case would require, almost by definition, some reference to the Administration's overall Alzheimer's strategy. Absent that, how can Congress know how the Administration intends to support the millions of families caring for those with Alzheimer's, and how this particular program does (or does not) contribute to that goal?

Referencing the $11 million in immediate cost savings is not, in itself, a sufficient justification for cancelling the programs either. After all, strong evidence from carefully conducted trials shows that support for caregivers can delay nursing home admissions and bring many other benefits. It's entirely possible that, scored correctly, these expenditures save the government far more than their cost in savings to Medicare and Medicaid.

These are not just academic questions. We have spoken with leading researchers that have pleaded for a clear national policy with regard to caregiver support. Currently they have to try to work with an array of agencies and a patchwork of programs – with each unsure of their own mandate and long-term support for such work.

Questions like these are fundamental. They are the kinds of questions that surface within the first hours of serious deliberation – as indeed they have for the Alzheimer's Study Group. This is an example of precisely the kind of overarching strategic discussion that has been missing far too long and that we cannot afford to neglect any longer.

Real Change Requires Real Change

The Alzheimer's Study Group was organized to address this lack of strategic planning. Our charge is to develop a National Alzheimer's Strategic Plan. Our intention is to spur the strategic conversation and planning that has been neglected for far too long.

The Study Group does not aspire to propose small adjustments to the status quo. Simply doing a little bit more of what we are already doing or doing it in a slightly better way will not bring us to where we need to be. If we want to see a real change in the impact of this disease upon our country, we need to embrace real change in the way we seek to overcome it.

That, in turn, begins with bold but disciplined strategic planning. The Alzheimer's Study Group is working to anticipate emerging trends and capabilities. Our aim is to capitalize

on them as quickly as possible to dramatically speed our current pace of discovery, development and delivery of better treatments and care practices.

Toward that end, the Study Group has selected five key areas that we will focus on as we craft our recommendations.

- *Encouraging Collaboration among Researchers.* Scientific researchers from academia, government, and industry need the tools and incentives to scan the growing body of Alzheimer's research for relevant breakthroughs. They also must be encouraged to more efficiently collaborate on solutions, regardless of organizational boundaries.

- *Improving Alzheimer's Clinical Trials.* Alzheimer's clinical trials must be better supported and coordinated to reduce delays, improve efficiency, and ultimately allow the faster identification of promising new treatments.

- *'Rapid Learning' from Large Electronic Health Datasets.* Cutting edge "data mining" tools and methods have the potential, if paired with the right information, to revolutionize how we prevent, treat and care for Alzheimer's. Our vision is of a bold, 21st century version of the Framingham Heart Study.

- *Integrating a Community-Based Care Model.* Innovative approaches to care have been proven to make a tremendous difference for those with Alzheimer's and their caregivers. Better ways to support patients and families, and help managing the cost of care must be developed from best case practices, and then made available to all Americans.

- *Providing Better Information to Policymakers.* Government leaders must be given meaningful and timely information on the mounting impact and potential responses to Alzheimer's if they hope to assess progress, set funding priorities, and exercise strategic oversight.

The Study Group has established working groups to develop recommendations based on each of these areas. Far from working in isolation, we have already worked with over a hundred leading Alzheimer's experts to assess where we stand today. We will continue to collaborate with these leaders and many others in the work that lies ahead.

We anticipate releasing our plan in early 2009. We request that you and your colleagues work with us to shape these recommendations and partner with us in their implementation.

Conclusion

I would like to conclude by thanking you again for this opportunity to speak with you about Alzheimer's disease, and the path we must embark upon to overcome it.

Alzheimer's is a crisis that mounts by the day. We have let too many of these days slip by without bold, decisive action to deliver meaningful relief to the millions of Americans struggling with this terrible disease. Together, we can end this sad legacy and replace it with a much better future for millions of Americans and our Nation as a whole.

The CHAIRMAN. Thank you very much. [Applause.]

Thank you very much, Speaker Gingrich.

We will turn to the panel now for questions. Senator Smith?

Senator SMITH. Justice O'Connor, many of us have watched the dignity with which you have dealt with your great husband, and obviously, now he is receiving care in an institution. I am wondering if during that process if you found any help, Federal programs, or support system there to lighten your burden or——

Justice O'CONNOR. Yes, a little bit. Senator Smith, we have switched John over to something called Evercare for the medical advice in the care center where he is, and it works quite well.

I don't know how many of you have had any exposure to that. But I have been pleasantly surprised, frankly, with the coordination of the advice and care that he is given and right in the center. He doesn't have to be hauled out to a specialist hither and yon. They have a coordinated medical program that comes to him, and it is helpful.

Senator SMITH. Is Evercare generally available?

Justice O'CONNOR. Yes, it is, and your staff can provide you information about it. I have been pleasantly surprised.

Senator SMITH. That is great news.

Speaker Gingrich, you gave us just a wealth of great ideas, and you asked us to prioritize the long list that you gave us. What would be one, two, and three that we ought to do?

Mr. GINGRICH. Let me say, first of all, I think that Evercare is a United Health product and is actually—has a remarkable record of improving lives, improving satisfaction, and lowering costs and is an example of the kind of breakthrough that the Center for Medicare and Medicaid Services should be routinely using to modernize the system across the whole system.

If I were prioritizing, the number-one thing I would do is change the way we get—the budgets work. The current budget process is insane. I use that word deliberately. I mean, I have had a long—as you know, a long experience up here. I am tired of being told we have to do things that are really stupid because we have always been stupid, and therefore, you literally don't sound appropriate if you are not stupid.

Senator SMITH. I have to admit, at 2 a.m., when we are voting on the budget, it really does seem stupid. But—[Laughter.]

Mr. GINGRICH. Well, you are forced in with the rules that are set up in black boxes that nobody holds accountable, and the Congressional Budget Office and the Office of Management and Budget force you into decisions that are irrational. So, if I were tackling one thing, I would tackle that first.

If I were tackling a second thing, it would be developing the ability to use the electronic databases because the amount we are going to learn when you start tracking 30, 40, 50 million people over 5 and 10 years and you begin to see various and sundry cross indicators we have never seen.

The third thing I would look at, I think, is this idea of a coordinator at the Federal level. The morning there is a coordinator who makes an annual report on Alzheimer's and who can actually list all the different Federal activities, you will be startled how much

you have on the table and how much you have at risk in not dealing effectively with this disease.

Senator SMITH. Thank you, Mr. Speaker.

The CHAIRMAN. Thank you, Senator Smith.

Senator Wyden.

Senator WYDEN. Thank you, Mr. Chairman.

Thank you, thank you both for an inspiring morning. Justice O'Connor, you speak for so many Americans who are trying to assist a relative, and we are just very grateful for your leadership.

Speaker Gingrich, let us go to the financing question, something you and I have talked about in the past because this, of course, has been the biggest challenge with respect to long-term care. The bills are crushing for the families. We haven't had sufficient private long-term care insurance. People fall between the cracks in terms of public services.

I want to ask this question this way. In the Healthy Americans Act, which is a bipartisan bill, the first bipartisan universal coverage bill we have had in the Senate, Senator Bennett and I make a special focus on the tax code, where we have between $200 billion and $300 billion go out the door in a way that disproportionately favors the most affluent and also rewards inefficiency. So we used that money to start making a transition to a more sensible, market-oriented approach in healthcare.

Are there any similar sources of funds that you could identify that we would zero in on and say this is a place where we can get more for our money and start moving it into the kinds of things that you and Justice O'Connor have spoken so eloquently about, particularly prevention and treatment?

That is what we did in terms of jump-starting the debate about universal coverage. How do we jump-start this question of funding the new investment strategy that I think you are spot on in calling for?

Mr. GINGRICH. In the Quality of Long-Term Care Commission that Senator Kerrey and I had chaired prior to the Alzheimer's Study Group, we looked at a number of long-term financing concerns because we have never seen, ever in history, a population that is going to live as long as people are going to start living.

A girl born in Japan last year on average will live to be 88. That means half of them will live to be over 88. I mean, no society in history has tried to deal with this.

As a totally different topic, I would be glad to come up and talk about it some day because it has all sorts of implications for Social Security, for retirement, for pension plans. I mean, we have to become a society with massively greater savings during our working years and probably with longer working years if we are going to be able—if we are going to have people who live to be 100, 110, and 120 who have a comfortable lifestyle.

My personal bias strongly favors a tax credit for quality long-term care, and I would even contemplate a tax credit that was, in effect, a part of what everybody did, almost like FICA, starting when you first went to work because I think we have got to find a way to quantify, buildup resources over a generation. So the generation starts taking care of itself.

I don't think you can have an intergenerational transfer system when you have a slowdown in population growth and people living 30, 40 years longer than they expected to. In 1900, the average age was 46. The average person lived to be 46 years old. So 100 years later, we have now added some 32 years to that lifespan. Nobody has ever tried to cope with this scale of change, and we are going to have to.

I will make a little bit of trouble and just say I have been astounded that the Congress has not taken seriously honesty in healthcare. The example I will cite for you is the New York Times did a four-part series 2 years ago on Medicaid in New York, where their estimate was that Medicaid in New York had 10 percent pure fraud. Not waste and abuse, not bad judgment—pure fraud. Crooks. People who were deliberately stealing. That is $4.4 billion a year in New York State alone.

HIV–AIDS transfusion in south Florida in three counties is clearly a stunning racket. There was one raid where the State and Federal Government collaborated. They closed down 17 infusion centers, five of which were pizza parlors. There is—my guess is that you have something like 10 percent of all Medicaid spending in the U.S. is fraud.

If I were looking for cash that would not cost the taxpayer, I would take seriously the New York Times study and just ask the question under what circumstance could you get that down to being, say, a 1 percent fraud rate. But that is a lot of money. I mean, 10 percent of all Medicaid begins to be a transferable amount of cash.

Senator WYDEN. Thank you.

The CHAIRMAN. Thank you very much, Senator Wyden.

Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman.

Thank you both for your excellent testimony.

Speaker Gingrich, when you were talking about the scoring that is done by CBO, I just could not help but think what a penny wise, pound foolish approach that we have. We know that in the long term these investments will save billions and billions of dollars. Yet when CBO does its scoring, it does its estimates as if nothing changes, as if human behavior does not change, as if the investment produces no results. I do think that that is something we need to change.

You brought up an issue today that most of us don't think about when we are thinking about Alzheimer's, and that is the National Science Foundation budget. Our approach, our focus has been on NIH. Could you talk a little bit more about why we should triple, as you recommended, the NSF's budget if we are serious about breakthroughs in Alzheimer's? Because I think that is not where we have traditionally focused our efforts.

Mr. GINGRICH. Brain science is particularly dependent on nonbiological knowledge. If you are going to—the ability to scan the brain while it is actually functioning is a direct function of physics and mathematics. The more breakthroughs you can make in getting very sophisticated models, the better off you are.

The human brain has about as many neurons as there are stars in the universe. That implies a level of complexity that is unimagi-

nable. Thinking through and dealing with that complexity involves an extraordinary amount of mathematics, which is an area you don't think of this as being part of the National Institutes of Health. Yet if you looked at the technology we use today, and you went back and said when was it developed and when did we understand the physics of that, most of that is done at the National Science Foundation.

The other area of breakthrough that I recommend highly is looking at nanoscale science and technology. Which is basically just very small, but the essence of it is down at the level of one atom or smaller than an atom. We don't fully understand—in fact, we don't understand much of anything about how it works, but we are very good at measuring what works.

Almost all the nanoscale breakthroughs originally were funded by either the Defense Advanced Research Projects Agency or by the National Institute for Standards, NIST, or by the National Science Foundation. Yet if we can get down to a point where we understand how one molecule works and how that relates to the development of plaque, if we can understand how one synapse is occurring and we can measure it in real time, we suddenly can start laying out an understanding, which I think affects, by the way, not just Alzheimer's, but it affects Parkinson's. It affects mental health.

It affects our learning—my guess is learning strategies 20 years from now will be totally different than the way we currently teach people, and it will all come out of this zone of brain science, which I think will be the most rapidly evolving area in science. I think that it will drive—much of its tools and many of its most powerful concepts will come out of National Science Foundation funding.

I am not anti-NIH, but I am saying I think we have really underestimated the importance of math, physics, and chemistry as the underpinnings of what we do at NIH.

Senator Collins. Thank you.

The CHAIRMAN. Thank you, Senator Collins.

Senator Whitehouse.

Senator WHITEHOUSE. I am interested, Speaker Gingrich, in your testimony about the results to be gained from coordination and electronic assembly, if you will, of the information that we already have on hand and the conclusions one can draw from it a la the famous Framingham study. Could you speak a little bit further about that? If you could, put Americans' concerns about the privacy of that data into context because that is an immediate concern of people who discuss this.

Mr. GINGRICH. Well, if you are going to look at the discovery of certain drugs recently which had unexpected side effects. Kaiser Permanente has had a significant role in discovering those because it has an electronic database, and so it can pick up pretty rapidly that there have been eight or nine bad outcomes scattered across the whole country. When you correlate them, they all turn out to be a person of a certain age using a certain drug. So, Vioxx, for example, was surfaced, in part, by correlating electronic data.

Now, as long as you depersonalize the data so I don't know who it is, and I am looking at a dataset of in the case of Kaiser 13 million and the case of the Veterans Administration about 21 million, in the case of Mayo it would be a couple of million plus, I am look-

ing at aggregated data that I can't track down who you are, but you have become part of set of information. I suspect most Americans would actually be glad to know that that kind of analysis was underway, and it has clearly saved lives in the recent past.

But nobody has—we don't invest today. We don't have a discipline of electronic epidemiology, where people are going out and developing large-scale studies and saying if I massage all this data, what do I discover about the interaction between diet, medicine, exercise, age, geography?

The other example which we will be developing this year, by the way, is that Gallup, working with Healthways, is now building the largest dataset in history on attitude about health. They are actually measuring 1,000 samples a day, 365 days a year. So, by the end of this year, they will have about 365,000 samples in which they are going out and asking people a whole range of health questions in order to begin to define which communities in America are healthiest and why and which communities in America have substantial health problems and why.

My guess is that 3 years from now, if you would take the electronic health records datasets and the Gallup Healthways dataset and match them, you would be startled at how many new public policy indicators we would have that literally do not exist today.

Senator WHITEHOUSE. I thank you.

Mr. Chairman, we had a wonderful meeting—hearing, I guess you would call it—a few years ago in Rhode Island on the general subject of electronic health records when Speaker Gingrich came, twinned with our wonderful Rhode Island State representative Patrick Kennedy in one of the more unlikely political strange bedfellows pairings that I have ever been privileged to witness.

But it demonstrates that this question of electronic health records and the information and savings that can be gleaned from them truly is a bipartisan issue. It is not right versus left. It is right versus wrong, or I think, as Speaker Gingrich has indicted, smart versus stupid. We have been on the wrong side of that for too long, and I appreciate his testimony.

The CHAIRMAN. Thank you, Senator Whitehouse.

Senator Dole.

Senator DOLE. Thank you, Mr. Chairman.

Speaker Gingrich, you submitted for the record long-term care financing. Would you elaborate on how the Alzheimer's Study Group plans to include suggestions for policymakers to address long-term care? Could you just give us a summary of what you think will be forthcoming?

Mr. GINGRICH. Yes, I think actually the Alzheimer's Study Group probably will not get too involved directly with that, except on the area of the community-based care model, where we do think we have to have innovative approaches to support patients and families. Because it—as you can tell from the list I read earlier, this is a very prestigious group of people.

Senator DOLE. Yes.

Mr. GINGRICH. I am not going to get in trouble by prejudging what they are going to submit. But I can promise this Committee that as soon as we have developed these ideas, we will submit them directly to the Committee for your knowledge. But as you

know, I am very seldom timid. In this case, I am unwilling to get very far ahead of the group because these are all powerful people, and they will get real mad at me.

Senator DOLE. Well, I think that might apply to my next question, which was in my State there is a respite group called Project C.A.R.E. That is Caregiver Alternatives to Running on Empty. They receive Federal funding, and I was interested in what the study group might be finding to be most valuable to the caregivers on a daily basis?

Mr. GINGRICH. Let me just say as you are trying to develop this, and I am speaking now for myself and not for the group. If you start with the idea, as Justice O'Connor said—and she may want to add to this—to the degree that we can make it easier and more affordable for families to care for people as long as possible, it is more humane. It is more desirable, and it is less expensive.

So if you were to erase the current system and say what would a system look like that maximized your ability? I think two of the things you would do is you would shift the financing to find ways to subsidize families who are prepared and willing to do this and to take on this great challenge.

The second thing is you would have a significant part of either NIH or the Center for Medicare and Medicaid Services actually trying to work in a collaborative way with the private sector to develop the technologies. One of the points that Meryl Comer makes is if it is your husband and they are larger than you, then just the single act of getting them back into bed is an enormous challenge.

Well, there are technologies that should be designable to modify homes to enable you to take care of that kind of a challenge, and all of that modification ought to be a tax credit because enabling them to stay for an extra year or 2 years will more than pay in avoidance of long-term care facility costs to help them.

So I think if your staff were trying—and we would be glad at the Center for Alzheimer's Information to work with you on this. But if you were to start from what is the ideal care that should be happening, and how could we finance and structure and how could we help invent the technology for that? Then, frankly, you want that technology to become commercializable——

Senator DOLE. Right.

Mr. GINGRICH [CONTINUING]. In a form where it is sold in retail stores at the lowest possible cost in a competitive environment. So I think that is how you want to design it. Then look at the current system, which is a fundamentally different system, and I also think, frankly, that a family based model has much less fraud and much less inappropriate use of resources than the institutionalized model.

Senator DOLE. Thank you very much, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Dole.

Senator Salazar.

Senator SALAZAR. Thank you very much, Chairman Kohl.

Let me ask a question to both Justice O'Connor and Speaker Gingrich, and that is if we look at the interim time period between now and the long-term finding of the cure. Some of the things we have talked about, that you have talked about in your testimony will require the kind of investment strategy that Speaker Gingrich

spoke about, the kind of development and use of electronic records and the like to understand the disease.

But in the interim, say, the next 10 years, are there things that you think we ought to be focused on in terms of diagnosis, in terms of caregiving to those who are afflicted by the disease now? What are those steps, those things that we ought to be doing at the national level here that deal with the immediacy of those affected by the problem in the next 10 years or so?

Justice O'Connor and then Speaker Gingrich?

Justice O'CONNOR. As far as I am concerned, I think we can hope for rather immediate response to the need to make the research more effective and to make it more likely that we can complete clinical trials on promising new approaches and do it quickly. Because as we pointed out, the returns are enormous if you can cut back by even 5 years the time that you are going to have to be totally incompetent as a person with Alzheimer's.

If you can reduce that by 5 years, you have made enormous gains, and we are on the threshold of that now. But we have to make the clinical trials broad based and more rapidly accomplished, and we have to provide the funding that will enable—I guess I learned something today. The National Science Foundation and NIH in a position to provide help right now for these things, not 20 years from now—now. Because we can save a great deal of Federal money if we just reduce the time that somebody has to be——

Senator SALAZAR. Let me sharpen my question, if I may, just a little bit. I understand the importance of doing that and those kind of investments. But there are, I think, among many Americans who have family afflicted by these diseases even the lack of understanding when they see a family member who is showing the symptoms of this kind of disease or for family members knowing what all their options are out there.

Today's effort, I think, is putting a big spotlight on this issue, and it is very important that we do that. But there are some interim steps, it seems to me, before we ultimately get to the results of our clinical trials, before we do whatever we can do with pharmaceuticals, before we look at major reforms in how we deliver healthcare to—in a long-term care setting. Those things are going to take time.

Are there things we could do immediately to help those afflicted by Alzheimer's and families today that would be something we could do for next year and the following year?

Justice O'CONNOR. Probably in the area of tax credits. For certain things, you could act very quickly.

Senator SALAZAR. So things like tax credits for family caregivers and the concept that Speaker Gingrich was speaking about previously.

Speaker.

Mr. GINGRICH. If I can add to that, and I think it is a very good question, and I hope I can be clear enough. First of all, to pick up on what Justice O'Connor just said, I think this idea of changing the resource flow.

If you were to bring in, and I think your staff could actually help structure this, and it is not necessarily something you do at a hear-

ing. But if you were to work with, say, the Alzheimer's Association and develop a series of where you looked family by family. What happens from the time—and again, some of you have had this experience in your own family. But what happens from the time you first learn about this diagnosis? What is the progression?

We need to build an anticipatory medical model where when it is something that we know is happening, we can get ahead of it. So, we can say, gosh, this means if you want to stay in your home, you probably need to think right now about refitting your home. OK? That should be a deductible expense or a tax credit, and you all ought to decide.

But my guess is, again, if you could win the scoring argument and you could say to the Congressional Budget Office, OK, if I can get people to be for every month they don't go to a long-term care facility, what could I afford to help their family with financially? You could almost immediately craft a tax policy that would be budget neutral or actually would be better for the budget.

Second, to the best of my knowledge, there is no place today where people can turn—and again, I think the Alzheimer's Association probably comes close to this. But there is no real place—we need a multilingual audio/video online capability to learn this stuff. As you know, it has got to be multilingual because it is not just about our language, but it is also about our cultural subsets because different groups learn different things in different ways, and they ask different questions.

People have got, we have got to find ways to get information out much faster and much more pervasively than we get it out today, and that means that it has to be Internet-based and iPod-based and cell phone-based. For the very poor, the cell phones actually are a very powerful medium of communication.

Third, you really want to have someplace working to popularize and commercialize technology. My guess is that the best technology for helping people care for people with Alzheimer's is stunningly better than the average technology, and the average technology is a lot better than what people who don't know anything are currently doing.

So, if you could accelerate—and places like the MIT aging lab are perfect examples of this. If you could accelerate the development—I, frankly, got this idea from the head of the MIT aging lab, who said to me one day, when these things are products and they are on the shelf at Wal-Mart and Costco and other facilities, then you have changed the world. As long as these things remain out here as professional things that you get only through a specialized company, you will never bring the price down, and you will never have this scale access.

Well, you have a marketplace of 6 million people and their families today. It is going to be a much bigger marketplace in 10 years. How do we get that marketplace to have access to the best technologies at the lowest cost so it becomes commonplace to have best care?

Last point I guess I would make because I do want to push back a little bit on one of your assumptions, and here I think that Justice O'Connor and I are absolutely in agreement. Even just making the breakthroughs on the next quality of medicine, making the

breakthrough on marginal improvements and getting it to every doctor is, in fact, an enormous blessing to the person who is in the middle of this.

I wouldn't undervalue that in the next 5 years we could have very substantial improvement in protocols and in medicines available in Alzheimer's, and that it is both a long-term breakthrough to get to the equivalent of a vaccine. It wouldn't be technically a vaccine, but to get to the equivalent of something that postpones it dramatically. But in the interim, there are a lot of steps that are more than palliative that make life dramatically better.

I think at a human level, we should not underestimate how do we accelerate the FDA, how do we accelerate the drug companies, and how do we accelerate the doctor learning about what is available as rapidly as it becomes available? All of these things will improve the quality of life now for people rather than 10 years from now.

Senator SALAZAR. Thank you.

The CHAIRMAN. Thank you, Senator Salazar.

Senator Coleman.

Senator COLEMAN. Thank you, Mr. Chairman.

First, Justice O'Connor, thank you. One of my favorite quotes is Maimonides, who once said, "Each of us should view ourselves if the world were held in balance and any single act of goodness on our part could tip the scales." I think you have led a life of tipping the scales. You tip them today, too, by shining a light on the caregiver, and I hope that folks are watching and read about this understand there are places to go and things to do and that we care.

Mr. Speaker, you talk about a community-based model. That is your thought about the benefit of folks being treated at home. A lot of your discussion on the funding side has been OMB/CBO. But CMS is a big player here. We have got—I represent a State that medical technology is a very big deal, and we are creating remote monitoring, a whole range of things.

Can you—I have been here almost 6 years. You were here for more than three times that. Can you talk to me a little bit about CMS, about how do we—I mean, for the things that are already out there or that are in the stages of being early development, how do we get them to be funded so folks understand what Senator Collins talked about, get away from the penny wise, pound foolish approach?

Mr. GINGRICH. Actually, my reflection, when you pointed out I have been here more than three times longer than you, was I felt much older, and I am now much more worried about things than I was when this hearing started. [Laughter.]

Well, let me go back to a piece that I said a while ago and give you a specific example. Don't underestimate how much the Office of Management and Budget is the enemy of fundamental change at the Center for Medicare and Medicaid Services. A letter was sent last year giving $100 million to a clinic in New Orleans with the specific provision that none of the money could be spent on information technology.

Now, given every speech the President has made on this topic, every speech Secretary Leavitt has made on this topic, that letter should be a scandal. That letter was directly caused by OMB. No-

body at HHS thought that was rational. So the power of relatively obscure bureaucrats who have hidden for 25 years and learned nothing to say no is enormous.

Second, I would suggest to you that part of what you want to do at CMS, and this would go contrary to some models of public bureaucracy, you need a lot more fellowship programs both to get CMS career civil servants out into the private sector and to get the private sector into CMS. I would try to look for a model, and I know that Andy von Eschenbach has been working this at the Food and Drug Administration, and he is exactly right.

We live in an era when you cannot have policy made by people who are 5, 10, and 15 years behind the curve. So, part of what I would look at is how can you dramatically open up the Center for Medicare and Medicaid Services both so if staff gets to go out and work at any one of a wide range of private sector things, but how many people from CMS have ever worked for Evercare? How many people from CMS have ever worked at a modern public hospital facility?

As opposed to they have been sitting in Baltimore—and these are decent people. This is not an attack on them as human beings. But if you spend your entire life in a risk-averse environment filling out paper, it is really easy to say no and not understand the human cost of the decision you just made. So I would look for literally reshaping CMS.

In my book "Real Change" and in a YouTube video called "FedEx vs. Federal Bureaucracy," I tried to outline the scale of change we need. If you look at the speed and accuracy of UPS and FedEx, which track 23 million packages a day while they are moving and enable you to go online and track them yourself at no cost, and compare that with the inability of CMS to do that and ask yourself why couldn't all Medicare funding be electronic? Every charge filed every night and have the same data flow that you get at McDonald's?

McDonald's files 37,000 stores worldwide every night. You would then be able to track—first of all, you would flush out fraud almost immediately. Second, you would begin to have all sorts of knowledge about what is really happening and what should we really be changing. It is a totally different model.

I would encourage you to look seriously at fundamental structural reform of CMS, and I would start by creating very substantial capacity for people to go out for a year of sabbatical and to bring in people for a year of internship in a way that would open the place up to a new generation of ideas.

Senator COLEMAN. Thank you, Mr. Speaker.

Thank you, Mr. Chairman. [Applause.]

The CHAIRMAN. Thank you. Thank you, Senator Coleman.

Senator Lincoln.

Senator LINCOLN. Thank you, Mr. Chairman, and thanks to both of you all for bringing your passion and interest here today and sharing it with all of us.

We also appreciate your work on the Alzheimer's Study Group. You know, this is a disease, however, those of us that are close to the disease know it all too well. But it is, indeed, a silent disease

until you become in contact with it, and then you begin to realize a little bit of what you have talked about.

I know Senator Grassley and I have worked on tax benefits for long-term care and the ability to encourage people to learn more. I guess that is my question is your recommendation on early education on Alzheimer's, not just on the effects of the disease. Obviously, that is critically important, and the Speaker mentioned training and if you could track the disease.

When my dad became so ill that we needed assistance in the home, my mother needed assistance, we found a woman who was unbelievable. Dad was her, I think, sixth Alzheimer's patient, and she stayed with all of her patients until they passed away.

But she could tell us the signs. She could say, you know, he is not going to be—he is going to be on these ups and down. We need to get him up. The weather is pretty. We need to get him outside because pretty soon he is not going to be able to do that. You can tell by the different things that you notice. Those are critical to quality of care, quality of life, but certainly, how you deal with the disease and the education of it.

So I guess my question is early education not just on the disease, but also on care expenses. Dad was diagnosed early. Mother didn't realize the expenses she was going to see, nor had she prepared for that, the advanced care planning. Some of the things that I think most people, quite frankly, or often people don't realize that Medicare has no funding for long-term care necessarily. They think Medicare is there, and it is going to be there for them in their golden years. But in terms of long-term care, it doesn't cover that.

So I guess if it is long-term care, in terms of both the care—educational component of the caregiving, but also the financial literacy that needs to be there in an educational component and how we do a better job of that. I think Speaker Gingrich, I think the statistic here in our country is for a baby girl that is born today in this country, she has a 50 percent chance of becoming a centenarian. My husband's grandmother will turn 111 in the next couple of months, and she still plays bridge 4 days a week, still lives on her own.

I mean, people are living longer, and we are going to see greater numbers. So this financial literacy, this education and care literacy is going to be critical not just when you see the disease, but before. Any suggestions on how we do a better job at that?

Mr. GINGRICH. Well, let me say, first of all, I think that is about as good a statement as I have ever heard. I think you did an extraordinary job just now. [Applause.]

I think you really captured a lot of different pieces. So I would almost suggest that we could start with you, and part of what you are saying is how could we have Alzheimer's caregivers in a way—and this is a serious example. The woman who came and helped your father, was she in a setting where she, in fact, could buildup a pension fund over time? Or was she an independent contractor in such a form that——

I mean, if we wanted to make it relatively easy to be an Alzheimer's caregiver, how could we build an ability, and this will go to something that Ron Wyden has worked on, but maybe to make it possible in every State to create an Alzheimer's caregiver coop

in a way that they could have group insurance. They could have pension buildup and a defined contribution. But to think about this group of people who are an integral part of what you are describing.

Second, your financial planning point is exactly right. There is a totality of life, and this is one of the great problems. This is why I suggested, and Rob Egge and I have been working on the idea of some kind of coordination. Nobody looks at the totality of this. So, you have different silos in the Government, each of which cheerfully runs around doing the best that it can at its piece, but, in fact, life is lived across the silos. So, the idea of developing, I think, that kind of approach is very important.

I don't quite know how to say this. When you go back home, just ask your audiences how many people have a cell phone with a camera. Then ask them how many of them have a laptop or some kind of computer. Nicholas Negroponte came by the other day, and I have a couple of his computers that were originally designed for the Third World that cost $187. Peru is buying one for every child in the country.

I sent it to my two grandchildren and got this wonderful phone call from Maggie, who is 8 years old, who said, "Oh, Grandpa, this package came, and I thought it was for mother, and it was for me." She and her brother Robert are now playing with this computer.

We haven't stopped and worked back from that is the potential we have to educate the country. We don't have to set up—if you go down and look at the Centers for Disease Control, which is a place I admire much and I have helped as much as I could over the years, you look at the way that people think, they still think in a paper-based bureaucratic, gradual model. You know, why do we put posters up somewhere?

You live in an age when what you ought to say is, gee, what is the Facebook application for Alzheimer's that everybody could have friends in a Facebook kind of model or a MySpace model. I am not company specific here. But we are living in a different world, and we don't know how to design a Government whose agility and information flow operates like that.

So, in a sense, you would like to be able to say—because you think about it. You have 100 Senators and 435 House members. You could literally communicate to every American. You could say to every American through your various techniques if you have Alzheimer's occur in your family, go to this site, and the site will lead you through how you can plan.

We need to think on that scale of creating democratic smality, democratic information for the entire country, leading them to commercializable, lowest possible cost tools to enable them to maximize the control over their lives. This is true, by the way, about much more than just the Alzheimer's patient.

But I thought what you said was really eloquent and really powerful, and I don't know that I can do much to add to it.

The CHAIRMAN. Thank you very much, Senator Lincoln.

Behalf of all of us on the panel, people here in the room and people all across America, we want to thank you both for giving us your time, your thoughts, and your passion here this morning as we move toward hopefully coming up with a cure for Alzheimer's

disease as well as treatment. Hearing from you today has made a big difference, and so giving us your time was very useful for something we know you care deeply about.

Thank you both for coming. [Applause.]

The CHAIRMAN. We will now move on to the second panel. The first witness on the second panel is Mr. Jackson, and I would like to ask Senator Smith to introduce him.

Senator SMITH. Thank you, Mr. Chairman.

As I said in my opening remarks, it is a particular pleasure I know for me, and I am sure I can speak for Senator Wyden on this as well, to welcome Chuck Jackson to the Aging Committee of the Senate. Chuck Jackson is age 50. He was diagnosed with early onset Alzheimer's disease. Since his diagnosis 4 years ago, Chuck has made it his goal to inform the American public about living with early onset Alzheimer's.

As a former member of the National Alzheimer's Association's Early Stage Advisory Group, Chuck is well known and respected for his insight and understanding of the issues that persons with the disease face.

So, Chuck, thank you for being here, and we look forward to hearing your testimony today.

The CHAIRMAN. Thank you, Senator Smith.

The second witness on this panel will be Suzanne Carbone. Mrs. Carbone is a family caregiver for her husband, Robert, and she works full time as a librarian in Rockville, MD. Prior to his diagnosis at age 70, her husband was dean of the College of Education at the University of Maryland.

Mrs. Carbone credits the support and services she received, including caregiver education programs, with allowing her to care for her husband for 10 years at home while also working full time. She is a native of Wisconsin, and she currently resides in Silver Spring, MD.

We are also fortunate to have with us today Dr. Rudy Tanzi. Dr. Tanzi is a professor of neurology at Harvard University and serves as the director of the Genetics and Aging Research Unit at Massachusetts General Hospital. He participated in the pioneering study that led to the location of the Huntington's disease gene, and he is credited with isolating the first familial Alzheimer's gene.

Dr. Tanzi is the fifth most cited scientist in the field of Alzheimer's disease research, and he was a 2007 recipient of the Ronald and Nancy Reagan Alzheimer's Research Institute Award.

We thank the three of you for being with us, and we will now take your testimony, starting with Mr. Jackson.

STATEMENT OF CHARLES JACKSON, ALZHEIMER'S PATIENT, ALBANY, OR

Mr. JACKSON. Good morning, Chairman Kohl.

The CHAIRMAN. Thank you.

Mr. JACKSON. Good morning, Chairman Kohl. Mr. Smith, thank you for inviting me here, and all the rest of you distinguished guests that are here to listen to what we have to say today.

I am Chuck Jackson. I am from Albany, OR. I was actually raised in the panhandle of Oklahoma. That is where this family picture I have relates. I took the liberty to bring that today because

I am speaking not only for these 14 people, my mother and her 13 siblings, but I am also speaking for my cousins and the other people that branch out from our family tree.

I have what is called the PSN2 genetics that came via what we call the Volga River Germans that had moved from Germany to Russia and then to the United States. They brought with them two or three of the genes that cause early onset with them.

More than 20 years ago, my Aunt Esther testified at one of the first Alzheimer's hearings held in Congress. Unfortunately, the former President Ronald Reagan later vetoed the legislation, and we have not done much since that time. My experience with Alzheimer's started in 1967 on myself. When I was 13 years old, I became my mother's caregiver. My mother Rachel had started and exhibited Alzheimer's similar to what my aunts and uncles had previously that I had been able to look at and see and be with.

I received a telephone call from my brother Danny in May of 2004. I was working at the time at Community Services Consortium as an employment specialist. He had gone through an experience or research with Dr. Rachelle Doody of Baylor University on a combination set of drugs called a cocktail, and he had done so well in the study on these drugs that at the end of it, she suggested that he call everyone in our family who was over the age of 50 let them know they had the family gene.

So he gave me the call that day, and I started going to my doctor to get on this set of drugs, this cocktail, to preempt the onset of the Alzheimer's is what we thought. In August of that same year, I was given a very bad evaluation by my employer. It was quite devastating to me, actually, because nobody had talked to me about it during the year or brought it up until that day, and after having worked there for 14 years with 95 and 97 percent evaluations from the past, it was really hard for me to take.

But that same—after that Friday, the next Monday, I had an appointment with my doctor to finish getting on the meds that my brother had called about. My doctor asked to see that particular papers that my employer had given to me in the evaluation. After looking at them, he asked me a question, "Have there been any other strange things happening in your life that you haven't told me?"

There were a few that I had planned to tell him, but when I would come in to see him, they just—I couldn't remember them. I couldn't talk about them. He looked up at me, and he said, "We might as well consider that you have already started the disease. We are not preempting it at this point." I really wasn't prepared for that statement from him. I was shocked.

I hadn't really been catching the signals I should, my body had been giving me. My family had not caught those signals, but my co-workers and my employer had. Now they thought I was doing things on purpose.

In the one—at one time that year, I had walked into the job site with a black shoe and a brown shoe on. Having gotten dressed in the dark, I thought I hadn't noticed the shoes. But my co-workers were laughing, and one of them finally walked up to me and asked, "Why are you wearing a brown shoe and a black shoe?" I glanced down, and I said, "I didn't know I was."

So my supervisor sent me home to change my shoes, which I did when I got home. When I got home, I put on the other pair of shoes that also happened to be one brown and one black and returned to the job. Of course, she was really angry at me.

There are things that I have learned during this time that I have gotten this diagnosis. I have learned how to live with the disease. I have learned how to adapt to it. I would like to say that the research that is available needs to be directed directly at the effectiveness of keeping a person in the home as long as possible after they have been evaluated by a doctor and having given a diagnosis of Alzheimer's because we are better off in the home than we will ever be in a care center, and we will last longer.

I once worked for the Burlington Northern Railroad in Montana. I am sorry. I know I have deviated somewhat from my written statement. I apologize for that, but I guess that is just kind of how it happened for me. I am now at age 54. I was actually 50 when I got my diagnosis. I am on Medicare at this time. It was a 2-year battle for us. My Representative Hooley's office helped me a great deal with that.

I am receiving Medicare, and I have a supplemental plan that I have bought from the PERS program there in Oregon so that my medications are taken care of as much as I can take care of them and my doctor's bills. I receive about $2,000 a month from two different disability programs. One is from Regency, which is a private program, and the other part is from my PERS retirement system. By the time I get done paying with my home and where my food costs and the medical costs, I don't have any money left at the end of the month. I think you should know that it is very costly to have this disease.

I have worked for the last 3 years to deal with this disease in such a way that we have quit thinking about it being an age disease. This is not—though there are more people over the age of 65 that have the disease, this disease is not an ageism disease.

Most people could get through life without having this disease and live to a long, long old age without any problems. But our society has come to a point where we believe that when a person gets to a certain age and they have Alzheimer's, that is normal aging. I want to tell you it is a disease. It is not normal aging. Otherwise, I would be 85 right now.

I know there is numbers of people with early onset in this country that have not been counted, and I often wondered why no one has ever counted how many people are actually involved in the disease in this country. But we have a fear of our Government and our friends and family knowing the disease that we carry in these families, and we try—well, our predecessors, my mother and my father's group of generation didn't want to talk about such things.

If we would have talked about this in the 1960's, we would have had more done today. But no one would talk about it. We have the ability in this country to put together a way for us to defeat this disease or at least make it available a good drug that will keep a person in the home at the same level as I may be functional today.

I mean, the small goal of going to the moon and back is—this is more or just as important as finding the moon and coming back to it. So it is imperative that the Congress keeps the Federal commit-

ment to Alzheimer's research now because I want to be an Alzheimer's survivor. I don't want to die with this disease. I would rather have a heart attack.

Much like the breast cancer survivors who are all alive today because of advance in cancer research and treatment, I would like to be a survivor of Alzheimer's. I would prefer or I want my daughter Rachel Jackson, that is with me today, not to have to live through this disease and not have to worry about it. I have taken this road mostly for her and then also for the untold thousands of us that are uncounted, that have not found a voice to tell people they have early onset Alzheimer's in their family.

My plea to you is that you support the Alzheimer's Association initiatives to get the research back on track so that we can stop this disease in its tracks and then find a cure for it.

I thank you for your indulgence in listening to me and your patience and the understanding that you are giving me.

Thank you. [Applause.]

[The prepared statement of Mr. Jackson follows:]

Statement of Chuck Jackson
Albany, Oregon

U.S. Senate Special Committee on Aging
May 14, 2008

Good morning Chairman Kohl, Ranking Member Smith and other distinguished guests. It is my honor to be here. My name is Chuck Jackson and I live in Albany, Oregon. I represent one of the hundreds of thousands of people in the United States with early-onset Alzheimer's disease. So far seventeen of my relatives have lost their battle with the disease – most before the age of 65. I am now living with Alzheimer's as is my older brother Danny, age 60, and three of my cousins.

More than 20 years ago my Aunt Esther testified at one of the very first Alzheimer's hearings held in Congress. Unfortunately, former President Ronald Regan later vetoed legislation that would have increased funding for Alzheimer research and provided programs to help caregivers - leaving the problems and challenges of Alzheimer's to be faced by later generations. At the time of my Aunt Esther's testimony I was working for Burlington-Northern Railroad in Montana and was unable to attend the hearing. I am here today to ask that you increase funding for Alzheimer's research and finish the work that my Aunt Esther started two decades ago.

My experience with Alzheimer's stated in 1967 when I was 13 years old. I became a caregiver for my mother Rachel who had started to exhibit symptoms of the "family disease" at the age of only 44. She died of Alzheimer's in 1973 at age 50.

My personal experience with Alzheimer's began in May of 2004 when I received a telephone call from my brother Danny who had already been diagnosed and was participating in a clinical trial at the Baylor College of Medicine in Texas. The trial was testing a combination of Alzheimer medications – similar to the cocktail therapy that had been developed for HIV/AIDS – and achieving good results. The researcher suggested that my brother tell other family members who knew they carried the Alzheimer gene to begin the combination therapy. I had learned in 2000 that I have a gene that would give me a 98% chance of getting Alzheimer's. I immediately went to my doctor to begin the process of getting on the cocktail medications.

Three months later, in August 2004, I received a bad performance evaluation at work. At the time I was employed by the Community Services Consortium in Corvallis, Oregon as an Employment Specialist helping laid-off workers find new careers. In my 14-year history with the Community Services Consortium, I had consistently received excellent reviews, scoring between 95 and 97 percent. However, in this meeting my supervisors informed me that my score was 75% and I was presented with a list of failures, including memory problems, poor organization skills, difficulty with speech and behavioral problems on the job. In a more comedic incident, I once came to work wearing one black and one brown shoe. Asked to go home and change, I came back to the office wearing the **other** black shoe and brown shoe which really annoyed my supervisor.

I was told that I had three weeks to improve my performance or I would be fired. Much of my work related to meeting people and establishing relationships with local businesses so that they

would hire the laid-off workers I was assisting. As a former AFL-CIO employee who had also experienced being laid-off, I had a strong desire to see others succeed and good people skills, which made the results of the job evaluation out of character and quite abnormal.

I immediately went to see my doctor. I told him about my poor job performance, that I had been having trouble with my vocabulary – forgetting words and not being able to find the correct words when I was speaking to people. I had also been experiencing problems with muscle control, my arms and legs would randomly go into spasms, and I was falling at times for no apparent reason. My doctor said that Alzheimer's had probably already begun to affect my brain and advised that I apply for disability benefits immediately. I returned to work the same day and completed the disability application. That was my final act at the Community Services Consortium. I was 50 years old.

Now at age 54, I'm on Medicare and receive disability benefits through CSC, my former employer, who has a private policy that pays 60 percent of my former salary. I also receive benefits from the Oregon Public Employees Retirement Fund. Though I am still living in my community and driving, I require the assistance of my former wife, Marianne, and daughter, Rachel, for some everyday needs. It is my goal to inform the American public and policymakers in Washington about the challenges of living with Alzheimer's. Focusing on the changes that need to happen to provide services and care for the growing population of younger individuals with Alzheimer's, I am an advocate for expanded services and more funding for research on early-onset Alzheimer's. I established and continue to lead a monthly Early Stage Support Group in Corvallis.

I have participated in numerous research studies including the "Pittsburgh Compound B" study led by Dr. Steve DeKosky and Dr. William Klunk. Federal funding is critical for studies like this that could potentially provide answers not only to those with early-onset Alzheimer's, like me, my brother, and cousins, but also for millions of other people facing the challenges of this debilitating illness. Unfortunately funding for Alzheimer research has declined every year for the last four years. Good scientific ideas are not being researched, young scientists and their new ideas are not being funded and life-saving treatments are being delayed or potentially lost forever. I can't understand why Congress is cutting back on funding for research when the costs of the disease and the number of people affected are going through the roof.

It is imperative that Congress increase the federal commitment to Alzheimer research <u>now</u> because I want to be an Alzheimer survivor – much like the breast cancer survivors who are alive today because of advances in cancer research and treatment. Otherwise my daughter Rachel or someone else from our family or even someone from another family will be back here in a few years, sitting in this same chair, making the same plea. History does not – and should not – have to repeat it self. As a country, we can do better.

Thank you again for giving me the opportunity to speak to you today.

The CHAIRMAN. Thank you, Mr. Jackson.
Mrs. Carbone.

STATEMENT OF SUZANNE CARBONE, ALZHEIMER'S PATIENT CAREGIVER, SILVER SPRING, MD

Ms. CARBONE. Good morning. Thank you for the opportunity to talk with you about our family's experience with Alzheimer's today.

My husband, Bob Carbone, was diagnosed with Alzheimer's about 8 years ago. Interestingly enough, he has an identical twin brother who has no symptoms of the disease. Bob was born in Plentywood, MT, where his immigrant father was a section foreman for the Great Northern Railroad, and his mother was a homemaker.

Bob earned a master's degree from Emory University and a Ph.D. from the University of Chicago. He was a special assistant to President Fred Harrington at the University of Wisconsin, and later he became the dean of the College of Education at the University of Maryland.

He was always very interested in the political process, and so he actually ran for the Maryland State legislature in 1982 and garnered a very good percentage of the votes. In January 2007, Bob moved into assisted living when caring for him at home was no longer an option. Today, he can no longer speak a coherent sentence. He cannot dress himself. He cannot take care of his personal needs. My family and I are not sure if he recognizes us, and my family is with me today.

I am just one of millions of caregivers who are faced with difficult and heartbreaking decisions of care. Every day, I meet yet another caregiver who needs help and does not know where to turn. In fact, in the taxi this morning, we met another person who knew another person who has Alzheimer's. Everywhere I turn, people with whom I speak know people with Alzheimer's.

Upon a diagnosis, families are swept into a sea swell as they are confronted with the changing levels of ability and changing patterns of behavior of their loved one. My husband and I were no different. We left the neurologist's office with a few prescriptions and minimal advice. We should have been able to leave that office with something that said these are the areas in your life that are going to change, and you need to address these issues during Phase 1, 2, and 3 of this disease. Here are the best contacts. These are the top resources in your area to whom you can turn.

I am, therefore, convinced that we need to transform the way that we support patients and families caught in the tangles of this disease. I struggled to patch together a system of support, drawing on public and personal networks to cope with issues of physical and emotional care, financial and legal planning, transportation, driving, in-home care, daycare, and finally, assisted living.

It felt as though we were on shifting sand because as soon as I had a care plan in place, my husband's needs would change, and then we had to seek out additional solutions to our situation. On top of that, we would have to convince him to accept the new solution.

One of the most useful resources that I found was a 6-week caregiver training program funded in part by a grant from Montgomery

County, MD, the Department of Health and Human Services, Aging and Disability Services. From it, I learned about the process of dementia, its stages and treatments.

I learned about communication needs. I learned about techniques to use during various stages of the disease. We had someone talk about environmental modifications to one's home. Finally, I learned about hiring and working with in-home care, daycare, respite care, and assisted living.

These workshops were invaluable, and they provided me with insight, information, skills, support, and contacts. Actually, the people who attended these workshops became a support group for one another. I urge that this type of program serve as a model and be replicated widely in local communities.

I am still working full time as a manager at the Rockville library in Montgomery County, MD. I must work in order to pay for the care that my husband receives. He receives excellent care, but the costs are huge—$73,000 last year.

If I become ill, how will we manage? Given the fact that my husband's father lived to be 100, it is entirely possible that he will outlive me. Then the cost of his care will be passed on to our two children. We must find ways to help families with this tremendous financial burden.

In conclusion, I look forward to the day when there are stronger, more cohesive community-based networks of resources to support patients and families with Alzheimer's. I am encouraged by the idea of memory centers, which I am just beginning to learn about, as seen at several universities throughout the country.

These could provide access to evaluation, diagnosis, and treatment, as well as a whole system of referrals to caregiver services and support groups. I wish that we had had such a resource for Bob.

I urge Congress to immediately increase the investment in research to find better ways to diagnose and treat Alzheimer's. I call on policymakers to pass legislation to support individuals with Alzheimer's and their families, especially legislation that would develop and improve patient-based customized care plans, provide families financial assistance in caring for loved ones with Alzheimer's disease, and that expands paid leave for caregivers.

Thank you very much for the opportunity to share a portion of our family's experience with Alzheimer's. I commend you for holding this hearing on this very critical issue.

Thank you. [Applause.]

[The prepared statement of Ms. Carbone follows:]

Senate Special Committee on Aging

May 14, 2008

Testimony on Alzheimer's Disease

Suzanne Carbone

Good morning. Chairman Kohl, and other distinguished members of the committee. My name is Suzanne Carbone. Thank you for the opportunity to talk with you about our family's experience with Alzheimer's disease.

In 1906 Dr. Alois Alzheimer presented the clinical and pathological characteristics of the first case of what would later be termed "Alzheimer's disease". At this time—over 100 years later—no effective diagnoses or treatment exists to prevent, reverse, or stop this devastating disease that robs patients of their identity and robs families of their loved ones.

My husband, Bob Carbone, was diagnosed with Alzheimer's eight years ago. In many ways, his story is a classic American success story. He was born to in Plentywood, Montana, where his immigrant father was a section foreman for the Great Northern Railroad and his mother was a homemaker. Relying on his sharp mind and love of learning, Bob earned a Masters degree from Emory University and PhD from the University of Chicago. He was the Special Assistant to President Fred Harrington at the University of Wisconsin, and before his diagnosis, was the Dean of the College of Education at the University of Maryland. Always interested in the political process, he ran for the Maryland State Legislature in 1982.

In January 2007 my husband moved into assisted living, when caring for him at home was no longer an option. I am just one of millions of caregivers who are faced with such a difficult decision. Every day, I meet another caregiver who needs help and doesn't know where to turn. Our country is not prepared for the emotional, physical, and financial impact of this disease.

I am here today to share with you some of the emotional, and financial impacts that Alzheimer's disease has on patients and families, to recommend a new model of support for patients and families, and to urge policymakers to immediately increase the investment in research to find better ways to diagnose and treat Alzheimer's.

Alzheimer's is a confusing, inconsistent and deceptive disease. It slips into households across America like a sly ghost. Before the diagnosis, I sensed that our lives were beginning to be affected by something I did not understand. The changes in behavior in my husband over many years were, I now realize, not because of lack of love for me, nor were they, as they most certainly seemed to be, symptoms of marital discontent. The changes were part of the disease, and the result of his fear and confusion as he became aware that some part of his mind was shutting down, and that the ghost of Alzheimer's was beginning to inhabit his being

Ultimately, my husband was diagnosed with Alzheimer's. However, since we still do not have adequate diagnostic mechanisms to differentiate between Alzheimer's and other dementias, how can we be sure it's really Alzheimer's, and how can we be sure he is getting the treatment he needs. According to Katie Masloow's study for the Alzheimer's Association, Alzheimer's Impact on the Nation: Prevalence, Cost and the Leading Issues in Clinical Care and Caregiving, "...most people with Alzheimer's disease and other dementias do not have a diagnosis in their medical records."

Upon a diagnosis, families are swept into a sea swell as they are confronted with changing levels of ability and changing patterns of behavior of their loved one. My husband and I were no different. Bob left the

neurologist's office with a few prescriptions and an admonition from the doctor to be "good to me", as he explained that our experience with Alzheimer's would be easier for Bob than it was for me. I left with a determination to extract something positive from this devastating news.

With the perspective that I now have, I am convinced that we need to change the way we support patients and families caught in the tangles of this disease. I struggled to patch together a system of support, drawing on public and personal networks, to cope with issues of physical and emotional care, financial and legal planning, transportation and driving, in-home care, day care, and finally assisted living. I felt we were standing on shifting sand, because as soon as I had a care plan in place, my husband's needs changed, and I would need to seek out yet additional solutions to our situation.

The Alzheimer's Association provided useful support, but I urge that it develop stronger community-based networks of supports among stakeholders, so that families have quick and visible access to the resources they need on a local level. My husband and I should have been able to leave the neurologist's office with something that said, "These are the areas of your life that will change and that you need to address during phase 1, 2, 3, etc. of the disease. Here are the best contacts, the top people in your area, i.e. Montgomery County, to whom you can turn."

One of the most useful resources I found was a six-week care giver training program I attended in 2006, created by Judy Hennessey for the Alzheimer's Association, and funded in part by a grant with the Montgomery County, Maryland Department of Health and Human Services, Aging and Disability Services. It was called Meeting the Challenges of Dementia: A Hands on Training Program for Family Caregivers.

In this training program I learned about the process of dementia, its stages and treatments. I learned about communication needs and techniques to use during various stages of the disease, about environmental modifications, needs during the middle and late stages, and finally, issues of hiring and working with in-home care, day care, respite care, and assisted living.

The care giver workshops provided skill development and acted as a support group for participants, providing a forum for participants to share their stories and learn strategies for coping with what is ultimately, the loss of people we love. The workshops were an invaluable experience, and provided me with insight, information, skills and contacts. I urge that this type of program serve as a model and be replicated and distributed widely.

I am still working full--at a time as a manager at the Rockville Library in Montgomery County, Maryland. I must work in order to pay for the care my husband receives. He now lives at Brooke Grove Assisted Living in Olney, Maryland, where he receives excellent care. However, the costs are huge, and this past year, they amounted to $73,000. If I become ill, how will we manage? I must stop working sometime, at some age, and given the fact that my husband's father lived to be a hundred years old, it's entirely possible that my husband will outlive me, at which time the responsibility of his care would be passed on to our two children. We must find ways to help families with this tremendous financial burden.

In summary:

1. I support the extraordinary efforts of the Alzheimer's Study Group in its efforts to develop a national strategy to address the multiple issues of Alzheimer's disease. I have read the documentation on their work, and hope that I can contribute to their effort in some way.

2. I support the development of community based networks of support; accessed through Memory Centers (similar to Cancer Treatment Centers). Please note the Memory Center at the University of Wisconsin model. This would be the entry into a system which would specialize in preventing and treating dementia. (At this time, there is disagreement whether it should be neurologists, geriatricians, psychologists.) It would also act

as a referral center to the host of support services patients will need as the disease progresses. These might include, for example, local chapters of the Alzheimer's Association, replications of The Friends Club (Bradley Hills Presbyterian Church model), financial planning advocates, elder care lawyers, case workers assigned to help families navigate through the system of resources.)

3. I urge the improvement of patient-based, individualized care plans (exercise, brain games, photos of family, structured environments with customized goal-setting for individuals.) Care centers say they have plans for patients but they are not adequately staffed nor applied, and most patients are still treated as a group, rather than as an individual. We need more health care workers in the labor force who are specially trained in Alzheimer's care, similar to proposals put forth by you, Senator Kohl, and your colleague Senator Boxer.

4. I appreciate that legislation authored by Senators Mikulski and Menendez is currently pending, to provide families financial assistance in caring for loved ones with Alzheimer's disease, and encourage Congress to act on these bills immediately. I also encourage Congress to expand the existing Family and Medical leave law to provide paid leave for family caregivers and understand that legislation in currently pending on this issue.

I thank you for the opportunity to share a portion of my family's experience with Alzheimer's, and commend you for holding this hearing to draw attention to this critical issue.

The CHAIRMAN. Thank you, Mrs. Carbone.
Dr. Tanzi.

STATEMENT OF RUDOLPH TANZI, Ph.D., DIRECTOR OF GENERICS AND AGING RESEARCH UNIT, MASSACHUSETTS GENERAL INSTITUTE FOR NEURODEGENERATIVE DISEASES, PROFESSOR OF NEUROLOGY, HARVARD MEDICAL SCHOOL, BOSTON, MA

Dr. TANZI. Thank you, Chairman Kohl and Ranking Member Smith, for giving me this opportunity today to provide an update on Alzheimer's research and particularly our focus on how studies of the early onset genes of the type that affect Mr. Jackson have more than any other piece of knowledge in Alzheimer's taught us about the causes of this disease and have guided current clinical trials, some of which I think are very promising.

Twenty-five years ago at Harvard Medical School, when I was a student, I had focused my attention—this is during the early days of the human genome mapping—on trying to identify the genes for early onset and familial Alzheimer's. In 1987, we discovered the first Alzheimer's gene called the amyloid precursor protein. In 1995, we discovered the exact gene mutation that runs in Mr. Jackson's family by studying the DNA from the Volga German families of which your ancestry comes. That gene and the other genes that we have looked at have taught us so much about this disease.

But before getting into the science, first I wanted to mention that none of the discoveries or drug trials I will mention this morning would have been possible without the courageous involvement of patients like Mr. Jackson and their families. We could do nothing without them.

This is also why the Genetic Privacy Act and GINA is so important because it allows families to participate without fear of discrimination. I do think that GINA could go farther toward long-term care insurance. It covers employment and health insurance, but long-term care is what many folks with Alzheimer's need, and so it would be nice to see that expanded even farther into long-term care insurance.

Second, I think is very important to emphasize that even though Alzheimer's drugs today are in trials after being developed by pharmaceutical companies, the original seeds of creativity and of basic biological and genetic discoveries almost all came from academic research. So, it is important to remember that while the big pharma and biotech take the drugs to clinical trails and bring them to the market, which is immensely important, if we dry up funding or don't have sufficient funding for the academic institutions, the basic research funded by NIH and nonprofit foundations, you basically dry up the pipeline. The seeds of creativity almost inevitably come from academia with nonprofit and Federal funding.

Third, I want to just mention that history has taught us that it takes about 20 years for basic research to evolve on and reach a stage of clinical trials, new drugs, and patients. This is exactly the case right now in Alzheimer's. The first Alzheimer's gene was found in 1987, more in the early 1990s, and now here we are in 2008 and some of the first clinical trials testing drugs that would treat the disease itself, not just the symptoms, are underway.

So what did we learn? Well, if we look at the three early onset genes that we know about, they all lead to the same culprit. That culprit is a small protein called A-beta, also called the amyloid beta protein. This small protein A-beta ultimately, in the end, gets deposited in the senile plaques. But we are learning most recently is it is doing most of its damage before it gets into the plaque.

So we used to concentrate more on the plaques as the battleground, but now we are seeing that small assemblies of this A-beta protein as they stick together—2 of them, 3 of them, up to 12 of them stuck together—go into synapses. In these synapses, nerve cells are trying to communicate, and they create short circuits. So they actually short circuit the neural circuitry, and this leads to cognitive dysfunction.

So what we have seen over the last few years is that the battleground has been moving away from the plaques and more toward the actual nerve connections or synapses, where this A-beta protein gets in the way of normal neurotransmission.

Now, current Alzheimer's drugs are in the category of better than nothing. They treat the symptoms. There is usually minimal benefit and is usually temporary, as most families can attest to, and caregivers. But, now, there are several Alzheimer's therapies that are in trial that are aimed at hitting these toxic A-beta proteins in the brain.

So if you think about it, OK, if the problem in Alzheimer's is you have an excessive accumulation of the A-beta protein in the brain, how do you fix that? Well, there are three different ways. You can limit the production of the A-beta in the brain, and that is being done with protease inhibitors. There are trials going on there.

You can try to clear the A-beta out of the brain as a second approach. The immunization approach is trying to attempt that, plus some other strategies.

Third, you can try to neutralize the toxicity of the A-beta. You can try to stop the most toxic form of it from actually ever taking root in the brain, and there are trials, testing, trying to hit that part of the pathway as well.

So I think the good news is on all three of these fronts, where we are trying to hit what looks like the major culprit as we learned from the early onset gene studies, that there are exciting trials in the works. I provided details about these trials, the companies that are doing them, their prospects, all in the supplemental information that was submitted to the Committee.

Now, again, I want to emphasize before closing that the most promising drugs we have in the pipeline that are in the clinic came from studies of these early onset Alzheimer's genes. Even though these mutations are rare, they have taught us more than anything about the cause of this disease.

All told, we know about four Alzheimer's genes, those three early onsets, plus one late onset one called ApoE. But these four genes account for only 30 percent of the inheritability of Alzheimer's. So imagine what we could do with the other 70 percent. I mean, if just these genes have taught us so much and most Alzheimer's research is focusing on these genes and their proteins, let us get the other 70 percent.

So my lab and other labs around the world are trying to find those other genes. We are specifically heading up what we call the Alzheimer's Genome Project, which is funded by the Cure Alzheimer's Fund and the NIMH. We have gotten longstanding funding for this from NIA as well. We have a paper coming out this summer that will describe our first results of some of the new Alzheimer's genes.

There are also other groups around the world who are all pecking away at this, working together, consortium—as a consortium to do this as well. So I am glad to say that geneticists are working together to solve this problem and get the rest of these genes.

The reason why, is that history has shown us every new Alzheimer's gene provides a new avenue for potential treatment. The gene teaches us about biological pathways that are going wrong in the brain. Now we don't want to go in there with drugs and change the gene. We are not talking about gene therapy.

When we find a new gene, it teaches us what is going wrong, and then we know how to fix exactly what is broken. Those are the trials that are going on now based on the early onset genes we have studied for the last two decades. Ultimately, the idea will be that these genes will also allow us to predict the disease early. So, thank God, GINA passed, and we hope it goes further.

We are converging now toward a personalized medicine approach. The vision would be to do genetic prediction and then to personalize treatment with a cocktail of drugs that hit different parts of the pathway to best treat an individual based on their genetics, their own genome. So the mantra would become "early prediction, early intervention."

Right now we are in the pioneering days of that vision. While there is good reason to be optimistic, there is also more work to do before we reach this goal, and scientists will need to work more closely than ever with clinicians, patients, the Government, nonprofits, and pharma to make this happen. We all have our role. We are well on our way, but the time to really push hard is now.

So thank you once again for giving me the opportunity to present.

[The prepared statement of Dr. Tanzi follows:]

PREPARED STATEMENT OF DR. RUDOLPH E. TANZI

Thank you Chairman Kohl and Ranking Member Smith. I am very pleased and honored to be here this morning to address the Special Committee on Aging.

I am a Professor of Neurology at Harvard Medical School and a geneticist at Massachusetts General Hospital.

Twenty five years ago, as a student at Harvard Medical School, I participated in the very first human genome mapping effort to locate a disease-causing gene. That gene was responsible for Huntington's disease, a horrible neurodegenerative movement disorder. Shortly thereafter, I focused my attention on mapping the genes for early-onset familial Alzheimer's disease, the type affecting Mr. Jackson.

In 1987, my lab discovered the first AD gene and we identified two more in 1995, all three causing early-onset AD. This morning, I will summarize the tremendous amount we have learned about the causes of AD and the ongoing trials of new Alzheimer's drugs made possible by studies of these early-onset AD genes.

Before getting into the science, I would like to make three important points:

First, none of the discoveries or drug trials I will mention this morning would have been possible without the courageous involvement of patients, like Mr. Jackson.

Second, few, if any, novel Alzheimer drugs being developed by the pharmaceutical industry today would have been possible without the original seeds of creativity and

basic biological and genetic discoveries that have come from academic research, primarily supported by federal and other non-profit funding for Alzheimer's research.

Third, it generally takes about 20 years for basic research findings to reach the stage of clinical trials in patients. This is the case for the discovery of the first Alzheimer's genes in 1987, biological studies of those genes, and current clinical trials in 2008.

By studying the genetic defects in the three early-onset AD genes over the past two decades, we have learned that the culprit in Alzheimer's is a tiny protein we call A-beta. As it accumulates to excessive levels in the brain, it short-circuits communication between nerve cells, ultimately killing them. The result is major cognitive dysfunction and memory loss.

While current Alzheimer's drugs only treat the symptoms offering minimal and only temporary benefit to patients, several new Alzheimer's therapies currently in clinical trials are aimed at actually stopping the progression of the disease by curbing accumulation of toxic A-beta molecules in the brain.

This can be achieved in three ways: 1. Limiting the production of A-beta; 2. Clearing A-beta out of the brain; and 3. Neutralizing A-beta's toxic properties. Novel drugs of all three classes are currently in clinical trials, including a promising one that my lab helped develop over the last ten years. And, I would be happy to provide more details about these therapies.

While I am optimistic about the success of these trials, history dictates that the first drugs out the gate are not always the best ones. We will clearly need to take many shots on goal to cure this disease; and, will most likely, someday, be prescribing a cocktail of different drugs to effectively treat Alzheimer's.

The most promising new drugs have been made possible from the knowledge gained from the studies of the gene defects causing early-onset Alzheimer's. However, these three genes together with one other (for late onset) account for only 30% of the inheritance of Alzheimer's disease. Imagine what we could do with the other 70% identified.

To find these, my lab at MGH is currently heading up the "Alzheimer's Genome Project", (primarily funded by a non-profit foundation and the NIMH). A paper describing the first set of genes is currently under review at a major scientific journal, and we expect to announce several novel Alzheimer's genes this summer. I would be happy to provide you with more details here, as well.

As history has shown, every new Alzheimer's gene provides a novel avenue for potential treatment while also improving our ability to predict risk for Alzheimer's early in life. Ultimately, the convergence of genetic knowledge and effective Alzheimer's drugs will allow for a "personalized medicine" approach to this devastating disease: "early prediction, early intervention." These are the pioneering days of that vision.

So, while there is good reason to be optimistic, there is also a lot more work to do before we reach our goal. Scientists will need to work more closely then ever with clinicians, patients, the government, non-profits, and pharma to make this happen.

Thank you.

The CHAIRMAN. Thank you. [Applause.]

Dr. Tanzi, is there a reasonable hope that we could one day find a cure for Alzheimer's? In the short term, how close are we to finding a way to delay the disease's progression?

Dr. TANZI. Well, I think most of the drugs that are in trials now that are trying to hit the A-beta protein have a chance to both treat the disease and our best hopes to reverse the disease. But they could also be used in folks whom we know are at risk before symptoms to prevent the disease.

I think that of the drugs in trials now, some of them have a chance of working. But it will only be the first wave, and we also know from history that the first wave is not always the best wave. But it opens the door to the next wave of drugs that do the same thing, but in a more potent fashion.

So my guess is that in about 5 years at least a couple of these clinical trials will bring us some drugs that work, but not necessarily the best ones. Then, over the next 5 to 10 years, they will open the door to new drugs that keep making improvements on these same mechanisms of action. I am hopeful that within 5 to 10

years, we will have a cocktail of drugs that will at least be stopping disease progression.

Then you have to trust that the brain can regenerate. That if you just stop the attack, that the brain has a chance to come back. I am optimistic about that. It is kind of controversial how well can the brain come back. Well, it really depends on when you hit in the disease. So, again, early diagnosis, early prediction becomes the key.

The CHAIRMAN. Well, if early diagnosis is so important, you are not recommending that everybody have a test?

Dr. TANZI. Well, I think that—I would think that 20 years from now, it would be routine that you know your genetic risk factors for the big diseases that threaten healthy aging—Alzheimer's, cancer, diabetes, cardiovascular disease. Then you will be already setting up for lifestyle changes, supplements, or drugs, if necessary, to prevent those diseases.

We don't have the genetic tests yet. These are still the early days, the foundational days, but everything is in place to come up with a good test. We don't have the tests yet to predict Alzheimer's, except in these rare early onset cases. But we are moving there, and we are hoping that the ability to reliably test and predict will dovetail with the drugs that come out of the knowledge gained from studying those genes so that we can empower patients with the ability to stop or prevent the disease once they have their test done.

The CHAIRMAN. Ms. Carbone, what advice would you give to those who are just starting to care for a loved one in this Alzheimer's?

Ms. CARBONE. Well, there were several things that happened when we received the diagnosis. The first thing that I did was to decide that we needed to make something positive out of this devastating news. Because my husband is a twin, we immediately tried to get into a twin study. So, I think you have to think about all the people who have this disease and see what it is that you personally can do.

My husband and I also renewed our vows. I knew that I would have to strengthen the commitment that we had to one another, and so that is a second thing that we did.

A third thing that I did was to immerse myself in everything Alzheimer's, and I read extensively. I attended every lecture I could find. I joined support groups, and I must say that I think that having the knowledge from other caregivers and sharing that with one another was really one of the strongest supports throughout this experience, and it continues to be.

But I would not be afraid of letting people know that you are a point person for Alzheimer's. We all need to be. So, if we can spread that idea throughout our society, I really would encourage everyone to do that.

There is an addendum that I would like to add, and I suppose it is because of my career as a librarian. But remember that libraries are very trusted institutions in this country. Remember that they provide the electronic access to information that Speaker Gingrich was also talking about.

In Montgomery County, we have a place, we have a Web site called Senior Site. Now if you think a little bit about how that kind of site could assist all of us with information in terms of distributing information about Alzheimer's, that is a way to distribute information throughout the country through the public library system.

Maybe there are other ideas like this. So those are some suggestions.

The CHAIRMAN. Thank you.

Senator Smith.

Senator SMITH. Dr. Tanzi, you, I think, rightly noted the importance of Federal funding as sort of the seed of research, and I am aware that it goes to many universities and, obviously, NIH. I wonder with those dollars, as discoveries are made, how well is that information shared, or is there some proprietary quality that takes hold when these things are discovered?

Dr. TANZI. When discoveries are made in academic institutions, our lifeline really is more funding, and that means publication. So we have to publish our findings for the good of science. Also there is the "publish or perish" rule. If you don't publish, when you try to renew your grant, it is unlikely that you are going to get a favorable review even for the best ideas because you have to show that you can finish the job.

So I don't think there is a problem in academia with sharing of information or publishing information. Particularly in Alzheimer's disease, I see that there is an increasing vector toward collaboration. All of the geneticists who used to compete in the old days to find the early onset genes, which were kind of the low-hanging fruit, are now working together to solve the more complex question of what are the various risk factors, genetic risk factors that work with the environment to cause the more common late onset form.

So I don't see holding proprietary information as an issue.

Senator SMITH. You see sharing as expanding?

Dr. TANZI. I think I see this, at least in my own world of Alzheimer's research and particularly in genetics and molecular studies, I think there is just a great trend right now toward it.

Senator SMITH. There are no impediments out there that we should be aware of?

Dr. Tanzi. No.

Senator SMITH. The marketplace of academia is working then?

Dr. TANZI. Yes, I think that it is great because if you look at all of the major drugs to come out of pharma, you will find a relatively low budget versus pharma budgets that lead to biological breakthroughs, the original seeds of discovery in academic institution using Federal and nonprofit funding——

Senator SMITH. How about research taking place abroad? How much collaboration and information sharing is there between the United States and other countries?

Dr. TANZI. Quite a bit. I don't want to sound too U.S.-centric, but I think that the research here is amongst the best, if not the best in the world. We do collaborate with, of course, folks in particularly in Europe and in Japan. But mainly for sharing in this case, for example, Alzheimer's family DNAs and reagents and things we

need to do our studies, we have international meetings all the time. The international Alzheimer's meeting this year will be in Chicago.

So it does go internationally. But I really consider this country the clear leaders in research.

Senator SMITH. Suzanne and Chuck, I really am touched by your personal stories, and thank you for having the courage to share them, one as a caregiver and the other as someone suffering from early onset Alzheimers.

Chuck, as I inferred from your comments, that your brother—I don't know whether he has early onset as well—but he encouraged you to participate in these trials. You did that. I didn't sense that you felt that was a very positive thing, and I wonder if it was or if I misheard you, if it was a positive thing? Do you recommend others with early onset participate in these trials?

Mr. JACKSON. Well, I am sorry if I misled you. It was very positive. My brother——

Senator SMITH. It was positive.

Mr. JACKSON. He was further along when they started the study than I am right now.

Senator SMITH. Does he have early onset as well?

Mr. JACKSON. Yes, he is 60, 61 right now. He is in Texas, in assisted living in San Antonio, TX. His wife lately had to leave him alone and go to Amarillo because her father, who is elderly, had some brain surgery. I wasn't able to tell her that I was going to be here until last night when I finally got a hold of her by phone to let her know where I was at.

Senator SMITH. It sounded to me also from your testimony that your experience with your employer was not necessarily positive as your diagnosis was being made. I wonder if there are some suggestions you could give to employers as early onset affects employees, some things that they might do to enable those who suffer from early onset to continue working longer and productively?

Mr. JACKSON. I think that is going to happen as more people get used to the idea that early onset is actually in the workforce. I know some people who have the diagnosis and diagnosed in their 40's that have been allowed to stay—their employers have kept them there, and the physician is the same physician that they had until they couldn't perform.

The problem with perceptions about Alzheimer's is some of our early onset problem in that most people don't think a person that looks as young as 45 or 50 or 55 can possibly have Alzheimer's. There is education that needs to be done in the local areas.

There is that little bit of reversed ageism on both sides of the fence with research. Most researchers limit the age of a person to be in a trial either at 60 or 55. Am I still correct on that? That leaves a lot of people that are in their 30's and 40's and 50's. I am not available to get into several different trials right now because I am 54 that are ongoing.

The researchers have looked at it as if there are two separate diseases out there. One is late onset and one early onset. I know that the companies that are doing the work are expecting a return for the research dollars and that the larger amount of people is in the older ages past 65 and that they are actually trying to develop drugs that affect that group. But if you read some of the research

numbers, you will find that more—more early onset people have been used in research that is then used for people over 65.

The problem has been for two things. A lot of people in their 80's—70's and 80's don't want to go into research. Also, that age group that came out of World War II, which is my mother's generation, born in the '30's and lived through the Dust Bowl and then World War II, they don't like to talk about their medical problems and history. They were silent about it in our farms because it was stoic and it was shameful to talk about having a disease like this.

My generation, as a baby boomer, I think I have been quoted in the New York Times as, "We are mouthy. We are not going to take this silently." That has kind of been where I have been at for the last 3 years. I am not going to go down silently. I would like the disease stopped before it affects my next generation, that we owe them something.

Senator SMITH. Well, you are showing great courage, and I am glad you are mouthy. That will benefit many in the future, Chuck, and we are grateful to you and to all of you who have been our witnesses today.

The CHAIRMAN. Thank you, Senator Smith.

Senator Wyden.

Senator WYDEN. Thank you, Mr. Chairman.

This has been a terrific panel. You all are really the face of the challenge—patients and caregivers and researchers and wonderful advocates. I just have a couple of questions.

First, Ms. Carbone, three cheers for librarians. My mother was a librarian. I think you all are really one of the country's great underappreciated treasures, and I so appreciate the thoughtful way that you have laid out what has affected your family. I am just interested in following up on one point.

Did you or your husband ever have a period where you tried to buy private long-term care insurance? The reason I ask because I was kind of looking over the chronology of events, and of course, these bills for long-term care are just crushing. I mean, it is easy for people to go through $60,000, $70,000 in a year.

What I wanted to ask because I saw that your husband ran for the legislature in 1982, and in 2007, then he moved into assisted living. At any point, say, after 1982, did you all investigate private long-term care insurance and look at how perhaps something like that would be useful for you?

Ms. CARBONE. I am so sorry that we did not take advantage of long-term care when we could, and I suppose that is the message. People need to plan ahead for this kind of impact on their lives. The answer is, no, we did not really seriously consider that we would need this kind of support.

Senator WYDEN. I am grateful that you are speaking out this way in a public forum like that, and I hope that message will go out far across the land because, clearly, this is something that can be of great value to families.

Now, there are a lot of challenges we know with private long-term care insurance as well. For example, in our bipartisan legislation, the Healthy Americans Act, we try to make sure, for example, there is going to be some inflation protection for families because what happens is they can buy a policy, and then all of a sudden

in a few years, it isn't worth a whole lot more than the paper it is written on because of inflation.

But I think that there needs to be a lot more awareness of this, and I think the fact that you are willing to come and publicly say that that was something that might have been of great help to you and your family is so important.

I think the other thing that I want the country to see is that if we don't have some private long-term care insurance in the future, what is going to happen is we are going to have two people who are going to need some assistance. Because I saw also in your testimony that you put in this grueling schedule. You are there working. Then on top of it, you are trying to assist your husband.

As sure as the night follows the day, when people are putting in essentially two full-time grueling, emotionally draining kinds of efforts like that, it is hard to do it physically. So——

Ms. CARBONE. There is a spiraling effect on the caregiver.

Senator WYDEN. Well, you have said it very well, and I just appreciate your being here.

Chuck, a question for you, and you put up that picture of your family, and I can tell there are a lot of Jacksons and the lineage goes back a long ways. But you are not just speaking for the Jackson delegation——

Mr. JACKSON. No.

Senator WYDEN. You are speaking for millions and millions of people, and it is a great service. We think you are an Oregon treasure, but you are really a national treasure. I just have a couple of questions for you.

What do you want to say to all those people in this country who right now are kind of fearful? They are a little bit reluctant to come forward. I notice now even with these new testing products that are available, and there are scores of new products out where you can test yourself, and I am sure some of them are a lot better than others, people are saying they are frightened about coming forward.

It is easy to see why they are frightened about coming forward because until we have a new policy that really zeros in on better prevention and treatment, they are worried about what is ahead when there is a diagnosis. So what would you like to say today to all of those who are fearful and reluctant to come forward?

Mr. JACKSON. OK. Let me think just a second. One thing that happens is our early onset group were not caught by our—people we were living with or married to. We were discovered by our employers. A lot of people before they even have the knowledge that they possibly can have Alzheimer's will be sent by their employer or go by themselves to get a diagnosis, and the doctor will tell them that they have a number of different things, including depression or a whole list of things before a doctor will finally say maybe we should find out if you have Alzheimer's.

I have friends of mine that I have met since 2004 coming to the forums and coming to the Alzheimer's Association who were diagnosed after 7 long years of searching from doctor to doctor and trying to skip from job to job that they had been laid off from because of failures in the job site, who finally gave them a diagnosis of Alzheimer's because they didn't know that they had it in their family history.

We had in our first meeting that my family attended here in Washington, DC, 3 years ago with Alzheimer's Association, we had—the first night we had a young woman, two young women and their father come in and sit down at our table. The next thing I know, one of them jumped around the table, grabbed me and hugged me, and said, "We are related." Her mother had Alzheimer's for 5 years, and they had come to that conference to find out if they could find the families that they were connected to that also were in the research study with Dr. Tanzi.

They found us that day just by chance, and ever since then, I have really thought there is ways—there is reasons for my being here today. The possibilities of finding a better test for a dementia test needs to be examined and researched for the people who are in their younger years because a lot of doctors don't want to turn around to someone that is 34, 35, 54, 45, "I think you might have Alzheimer's," until they have done all the other tests for any other thing that can happen to their body.

Does that make sense?

Senator WYDEN. It does. It seems to me, just as Ms. Carbone made people more aware of the need to look at private long-term care insurance and opportunities to plan for the future, what you have done, Chuck, is made it a lot more likely that people are willing to come forward, work with employers and family and be part of this new ethic of prevention and treatment.

I will close with one comment for you three, but I think it also goes to the whole discussion. It is not exactly a secret that in this Congress there has been a lot of brawling between Democrats and Republicans and pretty fair amount of partisanship.

What you all have done and Alzheimer's advocates, and particularly the Alzheimer's Association today, is you have really brought the Congress together. You brought the Congress together regardless of party, regardless of philosophy, that this isn't a partisan challenge. This is an American challenge.

This has been a terrific panel. Our thanks go to our Chairman, who consistently speaks up for older people and their families. Senator smith, my colleague from Oregon, as well, and I just want to thank you three. It has been a long morning. The room is not as full as it was 3 hours ago. But your views and your comments we are going to get out across the country because the American people need to hear them, and we thank you all for your service. [Applause.]

The CHAIRMAN. Thank you very much, Senator Wyden.

I would like to echo his comments of gratitude to you for the wisdom, the experience and knowledge that you have brought to the table here this morning, which will be transmitted—it has been out across our country.

Alzheimer's—disease it has been—a disease that, as we can tell from this hearing this morning, is of the greatest interest to everybody in our country for all the reasons that we have described this morning. Hearing you talk about it from your various vantage points makes a big difference and helps the process to move along considerably to get to that day that we are all looking forward to.

So we thank you for giving us your time, your energy. We appreciate all that you are going through and your contributions.

With that, the hearing is closed.
[Whereupon, at 1:11 p.m., the hearing was adjourned.]

APPENDIX

PREPARED STATEMENT OF SENATOR ROBERT P. CASEY, JR.

Mr. Chairman, thank you for scheduling this important hearing on Alzheimer's disease, a disease that afflicts millions of our older citizens and has a profound impact on their families and our nation. I also want to thank our witnesses for coming here today to share their stories, their experiences and their recommendations about how the federal government can better assist those living with Alzheimer's disease, as well as their families and caregivers.

The Alzheimer's Association estimates that 5.2 million people in the United States live with Alzheimer's disease and over 8 million individuals over the age of 65 will have it by 2030. Pennsylvania has the second oldest population in the country after Florida and it is estimated that 250,000 individuals are living with Alzheimer's disease in Pennsylvania today.

This is a significant number of people and as we all know, and as I'm sure Justice O'Connor and our other witnesses will discuss today, Alzheimer's disease does not just affect the individual living with it, but family members, friends and many others including caregivers who selflessly devote their lives and careers to caring for individuals with Alzheimer's disease.

There are almost ten million Americans caring for people with Alzheimer's disease and other forms of dementia. An additional 250,000 caregivers are children between the ages of eight and eighteen. This illustrates that burden placed on young family members when there is no one else to provide assistance.

With the aging of the baby boom generation, we can expect to see even more individuals diagnosed with Alzheimer's disease. It is estimated that one in eight baby boomers will develop Alzheimer's disease and this will put increased hardship and pressure on families, communities and our health care system.

While anyone connected to this disease feels the biggest cost in human terms, the economic cost is significant as well. It was estimated in 2007 that unpaid caregivers of people with Alzheimer's disease and other dementias provided care valued at $89 billion. Medicare spends more than three times on beneficiaries with Alzheimer's disease than any other disease and it is estimated that by 2010, Medicare spending on Alzheimer's disease will reach $160 billion per year.

There is no one single protocol that suits all patients with Alzheimer's. Every person diagnosed with this disease progresses differently and every person responds differently to treatment. This is why continued research is so critical.

Until we find a cure for this ravaging disease, we must work to ensure individuals with Alzheimer's disease and those who love and care for them receive the help they need. Hubert Humphrey always said societies are judged by how they treat the children, the elderly and the sick. We much continue to hold ourselves to his high standards and help those who cannot help themselves.

JUSTICE SANDRA DAY O'CONNOR RESPONSES TO SENATOR HILLARY RODHAM CLINTON'S QUESTIONS

Question. In your written testimony, you stated that caregivers of Alzheimer's patients are more likely to develop depression and suffer compromised immune systems. In your experience caring for your husband, John, what assistance has been most helpful in supporting your physical and mental health? What can the federal government do for caregivers like yourself across the country?

Answer. I have not sought help for my own physical and mental health thus far. I assume some medicare coverage will help if I do decide to consult a doctor. We must rely on our regular health care resources.

DR. RUDOLPH TANZI'S RESPONSES TO SENATOR HILLARY RODHAM CLINTON'S QUESTIONS

Question. You testified that the most fruitful research has originated from the study of early onset Alzheimer's genes, which enables you to delay the onset of people at risk. You also noted that it would be 20 years before genetic testing became routine. In the short-term, how do you recommend best identifying those at risk for Alzheimer's disease?

Could you provide us with more detail regarding new drugs that attack the toxic A-beta molecules in the brain? How soon will these drugs be available? Are they well-tolerated by individuals?

In your view, how critical is understanding the genetic causes of Alzheimer's in developing treatment and an eventual cure? Can you elaborate on the "Alzheimer's Genome Project"? What is the relationship between the "Alzheimer's Genome Project" and the NIH-funded Human Genome Project?

In your research, what have you discovered on the link between Traumatic Brain Injury (TBI) and Alzheimer's disease?

Answer. 1. With regard to how we can "best identify those at risk for Alzheimer's disease", currently, we can only predict risk with 100% accuracy in patients with early-onset (<60 years), familial Alzheimer's disease that carry a mutation in one of the three familial genes that we and other's discovered between 1987–1995. These three genes are the amyloid precursor protein (APP) and presenilin 1 and 2 (PSEN1 and PSEN2) genes. We presently know of >200 different mutations in these three genes, which when inherited, cause early-onset Alzheimer's with virtual certainty. These mutations are rare, accounting for only 1–2% of all Alzheimer's and half of the early-onset, familial cases, e.g. the type that afflicts the family of Chuck Jackson who also testified at the hearing on May 14, 2008.

The majority of Alzheimer's is the sporadic, late-onset (>60 years) form. We know from studies of identical twins, that at least 80% of the common ″sporadic″ late-onset form of Alzheimer's also involves inherited genetic risk factors. The only confirmed genetic risk factor in this category is the APOE gene. A risk variant of this gene, called "epsilon-4"occurs in ~25% of the general population and in ~50% of Alzheimer's population. Unlike the early-onset, familial gene mutations, inheritance of the APOE risk variant only confers increased risk for the disease, and does not guarantee onset. Thus, it is a "susceptibility" gene that requires other genetic and environmental factors to trigger, the disease. As such APOE is neither necessary nor sufficient to cause Alzheimer's, and is not intended for use as a diagnostic or predictor of the disease. It is only approved for use as a "differential diagnostic", i.e. for use in a patient presenting with dementia to help determine whether it is due to Alzheimer's disease. Neither APOE, nor any of several dozen "putative" and unconfirmed Alzheimer's genetic risk factors are approved for use as sole diagnostics or predictors of the common, late-onset, sporadic form of Alzheimer's disease. To someday reliably and accurately predict late-onset Alzheimer's disease, we must first "identify and confirm" the full set (likely dozens) of genetic risk factors that work together with each other (and environmental factors) to trigger this disease.

As an aside, it should be noted that companies like 23andMe, Navigenics, Knome, and DeCode are already charging considerable sums of money for anyone who wishes to pay to be tested for the "unconfirmed" genetic risk factors for Alzheimer's and other common diseases, e.g. cardiovascular disease, cancer, and stroke. In my view, it is highly premature and both medically and commercially irresponsible to be conducting these tests. To reliably predict disease risk, we will first need to establish the full set of "confirmed" risk factors and then determine how they work together to influence risk in a "multigenic" manner. As these companies become more popular, the public will need to be increasingly informed and educated about the fact these tests are not yet accurate, reliable, or scientifically sound. I am concerned that these tests may increasingly lead to unwarranted anxiety or a false sense of security about one's genetic destiny as these companies services become more "trendy".

In specific response to your question about how we can best identify the full set of genetic risk factors for Alzheimer's disease, we must first "identify" novel Alzheimer's gene candidates in genetic association studies and then attempt to "confirm" them by testing them for replication in independent Alzheimer's samples. We are approaching this in two ways. First, we have established a very successful and highly accessed website called AlzGene (http://alzgene.org), which is supported by the Cure Alzheimer's Fund. This site compiles and systematically displays all of the data generated in all available publications (>1600) that have addressed Alzheimer's genetics. Most importantly, for novel genetic risk factors that have not yet been confirmed but are gradually being tested for replication in multiple independent Alzheimer's populations, we compile all of the published data for the candidate risk fac-

tor and perform genetic analyses on the sum data to determine which novel genetic risk factors for Alzheimer's have the highest likelihood of being confirmed as *bona fide* risk factors for Alzheimer's disease. To date, over 1500 gene variants have been tested as genetic risk factors for Alzheimer's, of which we (AlzGene) have found that only 29 have yielded statistically significant results toward confirmation. Every week, we update these analyses with the ultimate goal of establishing the complete set of confirmed Alzheimer's genetic risk factors, which determine one's predisposition for the common, late-onset form of Alzheimer's. With the overwhelming success of AlzGene, we have established similar sites for Parkinson's disease (http://pdgene.org) and schizophrenia (http://szgene.org). The CDC has recently indicated interest in eventually doing the same for all common human disorders with complex genetics. For the success of all these efforts, Alzheimer geneticists will have to work closely with each other and patients and their families to test candidate risk factors in as many independent Alzheimer's populations as possible. GINA should go a long way in providing protection to patients and their family members who participate in these studies. However, GINA covers employment and health insurance, but not life insurance or long-term care insurance. Thus, I believe that there is still more work to do on a comprehensive genetic privacy act as we move into the age of personalized medicine. A second strategy for finding the remaining Alzheimer's genes is our Alzheimer's Genome Project, which is described in more detail below in answer #3.

With regard to when we will be able to do routine genetic testing for life-long risk of Alzheimer's disease and other common age-related disorders, e.g. stroke, diabetes, cancer, currently, we can already reliably predict many of the rare, early-onset, familial forms of these diseases, which generally represent 1–2% of these diseases. But, for the vast majority of cases, which are late-onset, we will first need to identify and confirm dozens of genetic risk factors that work in concert to determine one's life-long risk for disease. For Alzheimer's and other common, complex genetic diseases, we have established four "confirmed" genetic risk factors and are still investigating dozens of "putative" risk factors that have yet to be confirmed. To reliably and accurately predict disease risk, we will ultimately need the complete set of "confirmed" risk factors and we will need to understand how they work together in a "multigenic" manner. While great progress is being made, these are still the early and "pioneering" days of this effort. Great progress is being made via AlzGene, the Alzheimer's Genome Project and other Alzheimer's genetics efforts. However, given the scientific challenges of identifying and confirming novel genetic risk factors, I believe that it will take 5-10 more years to assemble the first reliable multigenic tests for late-onset Alzheimer's disease and other common, age-related, complex genetic diseases. Routine testing should be possible in 15–20 years. And once again, the genetic testing currently being sold by companies such as 23andMe, Navigenics, Knome, and DeCode is, in my opinion, entirely premature and scientifically unsound, and it would be prudent to educate the public about this. I and other geneticists are currently doing so through the media, e.g. in an upcoming episode of Nova on PBS.

2. The second question regards the new drugs that target toxic A-beta molecules in the brain. These drugs are aimed at retarding disease progression by curbing the accumulation of the neurotoxic protein, A-beta, in the brain. The four established AD genes (APP, presenilins 1 and 2, and APOE) have taught us that the common pathological feature in the AD brains of patients carrying defects in any of these four genes is the excessive of accumulation of neurotoxic A-beta. There are two basic ways to lower A-beta levels in the brain: Promote the clearance of A-beta from brain, or curb the production of A-beta in the brain. Details on the anti-A-beta drugs currently in development and their prospects for success are provided in a separate word file (Abeta—AD—drugs.doc).

With regard to the predicted timeline, I believe the first anti-A-beta therapies should hit the market in 2–3 years, but as is often the case with the first wave of therapies, these will not necessarily be the best ones. They will, however, open the door for more effective versions of anti-A-beta therapies, which should come on line in 5–7 years.

With regard to the question of safety, generally, I believe this class of drugs will be well tolerated with one exception. We will need to carefully watch for adverse events, e.g. micro-hemorrhages and encephalitis, from immunotherapy approaches involving active vaccination or passive immunization.

3. Regarding the third question of how critical is "understanding the genetic causes of Alzheimer's in developing a treatment and eventual cure", the vast majority of researchers and clinicians in the Alzheimer's field would agree that the contribution of genetics to solving the mystery of Alzheimer's disease has been unmatched and unprecedented. The genetic component of Alzheimer's disease is very

strong with at least 80% of cases involving inheritance, according to large twin studies. Most of what we now know about the etiology and pathogenesis of Alzheimer's disease has come from the discovery and characterization of the four known Alzheimer's genes (APP, PSEN1, PSEN2, and APOE). Moreover, most Alzheimer's therapies currently in development, e.g. anti-A-beta therapies have been made possible from studies of the four known Alzheimer's genes, particularly, three early-onset genes.

In 1987, we, and others, reported the isolation of the first AD gene (APP) then went on to co-discover two more early-onset genes (presenilin 1 and 2) in 1995. I wrote about these discoveries and their impact on Alzheimer's research in my book "Decoding Darkness: The Search for the Genetic Causes of Alzheimer's Disease" and would be more than happy to send the Senator and her staff a copy. In addition to these early onset genes, a late-onset genetic risk factor gene, APOE, was discovered in 1992. These four genes account for only 30% of the inheritance of AD with 70% still remaining a mystery. If one considers what the field has accomplished with the known genes, imagine what we can achieve with the remaining 70%. Every new gene we identify and confirm as a *bona fide* genetic risk factor in AD provides a new biological target for drug discovery while also enhancing our ability to predict and diagnose the disease. While, I am generally optimistic about the ongoing clinical trials of anti-A-beta therapies, we must ready ourselves for the possibility that they may not be sufficient to fully treat or prevent the disease, or may even fail. This is why we must identify the genes underlying the remaining 70% of the inheritance of Alzheimer's. As history has shown us, every new gene we can identify will provide another shot on goal to effectively treat, prevent, or even cure this disease.

To elucidate the complete set of Alzheimer's genes, labs all around the world are trying to identify the remaining AD genes. Toward this end, we are carrying out the AlzGene project (described above in answer 1 above) and the Alzheimer's Genome Project (AGP). The AGP, which is based in my laboratory at Massachusetts General Hospital, is a three-year, approximately $3 million effort mainly being funded by the Cure Alzheimer's Fund with additional support from the NIMH and NIA. We are scheduled to publish the first set of results by the summer of 2008. The AGP is the first family-based whole genome association study for Alzheimer's disease, being carried out in over 1300 AD families. This study requires the newest technology, e.g. microarray genotyping "chips", sophisticated statistical analyses, large family samples for DNA, and especially, the many databases made possible by the NIH-funded human genome project. The databases have been absolutely essential, if not indispensable, to the success of the AGP and other efforts like it. They provide details about individual genes as well as the structure and organization of the human genome. We need this information to interpret or genetic findings from studies of patients and their family members.

4. The fourth question regards the relationship between Alzheimer's and traumatic brain injury (TBI). After age, family history, and gender, the greatest risk factors for Alzheimer's disease are head injury and stroke. Over the past several years, we and others have discovered both stroke and TBI significantly increase production of the neurotoxic A-beta protein in the brain. This, in turn, leads to increased risk for Alzheimer's disease over the ensuing years following injury. In 2007, we published the molecular mechanism by which stroke leads to increased generation of A-beta in the brain. Over the past year, we have found that TBI increases cerebral A-beta levels in the same manner. Consequently, we believe that those who suffer from a stroke or undergo head trauma, e.g. soldiers in Iraq and Afghanistan, also incur increased risk for Alzheimer's disease. We are currently studying the molecular mechanism underlying the stroke/TBI-induced increase in A-beta in order to develop strategies to reduce A-beta generation immediately following brain injury. Such therapies could include the anti-Abeta drugs currently in clinical trials for the treatment of Alzheimer's. If successful, one could envisage a medical protocol in which patients entering the emergency room or soldiers undergoing TBI in the battlefield would immediately be given such drugs to help ward off downstream risk for Alzheimer's disease later in life.

Alzheimer's Drugs on the Horizon

By Dr. Rudolph Tanzi, Massachusetts General Hospital

Recent developments regarding drugs aimed at treating and preventing Alzheimer's disease (AD) by targeting the neurotoxic peptide Aβ.

This article, the first in a series of pieces reviewing promising new AD drugs in development, focuses on novel therapies based on the "Aβ Hypothesis of AD". These drugs are aimed at retarding disease progression by curbing the accumulation of Aβ in the brain. The four established AD genes (APP, presenilins 1 and 2, and APOE) have taught us that the common pathological feature in the AD brains of patients carrying defects in any of these four genes is the excessive of accumulation of neurotoxic Aβ. Aβ is generated by the action of two enzymes, beta- and gamma-secretase, which serially cleave the amyloid precursor protein to produce Aβ. If too much Aβ is produced in the brain, or if Aβ is not sufficiently cleared from the brain, excessive levels of Aβ accumulate and form neurotoxic aggregates (oligomers), which can impair neurotransmission at synapses, and kill neurons. There are two basic ways to reduce cerebral Aβ levels as a means for treating (and preventing) AD: either promote the clearance of Aβ from brain, or turn down production of Aβ in brain. Below, we review some of the more promising therapeutic candidates currently in clinical trials for treating AD based on reducing cerebral Aβ levels.

Promoting Aβ42 Clearance

These drugs are aimed at clearing excessive Aβ molecules out of the brain and/or blocking Aβ from forming neurotoxic aggregates.

There are five major trials in this category:

1. Aβ Immunotherapy (Wyeth/Elan and others)

In the Aβ immunotherapy approach, there are two basic strategies: active vaccination and passive immunization. Active vaccination involves immunizing a patient with aggregated Aβ, similar to the type that accumulates in the brains of Alzheimer's patients. This stimulates the patient to produce antibodies to Aβ. In the passive immunization approach, instead of immunizing the patient to make the antibodies targeted against Aβ, the antibodies are produced and purified in the laboratory and then injected intravenously into the bloodstream of patients. In both approaches, antibodies bind to Aβ peptides in the brain and blood and progressively reduce brain Aβ levels. The first clinical trial (Wyeth/Elan) using the active vaccination approach was terminated because several of those treated developed encephalitis. The alternative passive immunization strategy is believed to be safer and is being pursued by over a dozen different drug companies.

Furthest along is the large phase III trial at Wyeth/Elan (Bapineuzumab). While promising, this therapy can be relatively expensive. When one considers the demographics of AD, it is not clear whether the healthcare system will be able to support passive immunization as a long-term solution for the greater population given its cost. Patients would have to receive intravenous injections of the antibodies on a monthly or biweekly basis at considerable cost. Nonetheless, there is a fair chance that this strategy will provide benefit to AD patients.

Outlook: Excellent, but with a small caveat for safety issues based on some reports that accumulation of Aβ-antibody complexes on blood vessels can cause micro-hemorrhages. That said, so far, this does not seem to be a frequent enough event to curtail the trials, and patients are closely monitored for such events by brain imaging.

2. IVIg (Gammagard, Baxter International)

Another immunotherapy approach involves intravenous "IV-IgG" injections, which attempt to achieve the same goal as the Aβ immunization therapies described above. In this case, instead of injecting purified antibodies to Aβ that have been carefully prepared and purified, human donor plasma containing the entire set of antibodies is injected into AD patients. The expectation is that some of the antibodies (auto-antibodies) will be naturally targeted to Aβ. Clinical studies are in the very early stages. A 24-patient study unveiled last summer by Baxter showed 16 patients on Gammagard had a better cognitive response than eight patients on a placebo.

Outlook: Questionable. This approach is based on the speculation that there will be sufficient levels of natural auto-antibodies in donor plasma directed against Aβ. It is not as "clean" or specific as the targeted passive immunization strategy.

3. Alzhemed (Neurochem)

Alzhemed (Neurochem) is an orally available drug known as a GAG-mimetic, which is designed to bind to Aβ peptides and prevent them from aggregating. In this way, the drug is intended to block Aβ from aggregating into senile plaques. Phase II and III trials of this drug have failed, however, Neurochem may attempt a revised Phase III trial in the future.

Outlook: Poor. It is highly unlikely that this drug can be rescued.

4. PBT2 (Prana Biotechnology)

PBT2 (Prana) is a "metal protein attenuation compound" (MPAC) that strips zinc and copper from Aβ and thereby prevents Aβ from aggregating and from forming neurotoxic Aβ oligomers, which can impair cognition. The strategy is based on

the discovery by Cure Alzheimer's Fund Research Consortium Chairperson, Dr. Rudolph Tanzi, that copper and zinc are required for Aβ to aggregate into neurotoxic forms in the brain. PBT2, which competes copper and zinc away from Aβ, has been shown to dramatically reduce Aβ aggregation and accumulation in transgenic AD mouse models. It is also able to block the detrimental effects of Aβ on neuronal synapses, neurotransmission, and cognition. Phase IIa clinical trial results, which were announced in March (2008), were highly encouraging. After 12 weeks of oral administration in 78 mild-moderate AD patients, PBT2 significantly lowered levels of the most neurotoxic form of Aβ, Aβ42, in the cerebrospinal fluid (reflecting effects in the brain). Moreover, the drug significantly improved cognition in the treated AD patients (versus placebo treated) based on their performance on two neuropsychiatric tests for "executive memory". Importantly, the drug had no side effects or adverse events and was well tolerated. Prana, co-founded by Dr. Tanzi, is now seeking a big pharma partner to proceed to a larger phase IIb (or phase III depending on the partner) clinical trial of PBT2.

Outlook: Excellent. PBT2 has the added benefit that it can be taken orally.

5. AZD-103 (Transition Therapeutics)

AZD-103 (Transition) is a sugar-like compound known as an "inositol" that is aimed at breaking down Aβ aggregates. In a phase I clinical study, AZD-103 was well tolerated. Transition as now partnered with Elan to carry out a phase II clinical trial.

Outlook: Fair. The mechanism of action by which this drug works is unclear and relatively non-specific for Aβ.

Regulating Aβ Production

This class of drugs is aimed at regulating the generation of Aβ in the brain.

1. LY450139, gamma-secretase inhibitor (Lilly)

LY450139 is a gamma secretase inhibitor (GSI) targeted at blocking the activity of gamma-secretase, an enzyme necessary for the production of Aβ. While this particular drug has done quite well recently proceeding all the way to phase III clinical trials, this class of drug has generally been shrouded with potential safety concerns. This is because the enzyme, gamma-secretase, is normally needed to process many other proteins beyond the APP. For example, gamma-secretase is required to processes the essential protein called Notch. When this event is blocked, the result can be skin cancer. Yet, the fact that Lilly's candidate has made it all the way through to phase III trials would attest to its safety.

Outlook: Good. It will still be necessary to monitor this drug for potential side effects of blocking gamma-secretase activity.

2. Flurizan (Myriad)

Alternatives to GSI's are "gamma-secretase modulators" (GSM). This class of drugs also targets gamma-secretase, but instead of inhibiting overall gamma secretase enzyme activity, GSM's "modulate" gamma secretase enzyme activity. More specifically, this class of drugs allows gamma-secretase to carry out its normal functions, including the production of Aβ40, but selectively block gamma secretase's ability to produce the neurotoxic form of Aβ known as Aβ42. In the brain, ~90% of the Aβ made is Aβ40 and ~10% is Aβ42. Aβ42 is considered the more dangerous form of Aβ because it is able to aggregate more readily into neurotoxic forms. All but a handful of the early-onset, familial AD mutations in APP and the presenilins (which are a part of the gamma secretase enzyme complex), have the same pathogenic effect: they increase the ratio of Aβ42:Aβ40 in the brain.

Ibuprofen (and other non-steroidal anti-inflammatories; NSAIDs) were first reported to have GSM properties, i.e. they lower the Aβ42:40 ratio. Clinical trials were carried out for ibuprofen and mostly failed. Myriad then developed a NSAID-like drug called "flurizan". While the Phase II trial did not show statistically significant effects on AD, high doses showed some benefit. Thus, phase III clinical trials with high dose (800 mg) flurizan are underway with reports expected this year. Given the large size of the phase III flurizan trial, it is possible that statistically significant endpoints for cognitive improvement might be obtained, in which case, flurizan may head toward FDA approval for the treatment of AD.

Outlook: Fair-Good. While GSM's as a class of drug are very promising for treating AD, flurizan is not particularly effective based on its poor performance in Phase II trials. However, it is possible with the large size of the Myriad phase III trial using a high dose of this drug (for which some cognitive improvement was noted in the phase II trial), this drug will improve cognition with sufficient statistical significance to allow it to make it to the market. It is doubtful, however, that the benefit will be any greater than currently available AD drugs, e.g. aricept and namenda, given the relative low potency of this GSM.

3. E2012 (Eisai)

E2012 is a novel, more potent gamma secretase modulator than Flurizan. It was developed by Eisai (who also brought us Aricept) in a partnership TorreyPines Therapeutics (TPTX). Eisai carried out a screen for novel GSM's in parallel with TPTX while also licensing first rights to TPTX's GSMs. E2012, which has the same core structure as one of TPTX's lead GSM's, was advanced into a Phase I clinical trial by Eisai. In February 2007, the E2012 trial was put on hold because

some side effects were observed in the eyes of rats after 13 weeks of treatment. After further testing, the side effect was not observed and the hold was lifted in April 2008. The drug is now headed back into a Phase I clinical trial. Meanwhile, TPTX and other drug companies, e.g. Merck and Lilly, are developing additional GSMs.

Outlook: Excellent. Based on preclinical studies in AD transgenic mice, high-potency GSM's appear to be very effective at curbing disease progress and AD pathology. While Myriad's GSM, flurizan, described above, may turn out to be the first GSM to make it to the market (pending Phase III trial results), it should be noted that it is not a very potent GSM. Nonetheless, flurizan may serve to "open the door" for more potent GSM's and other anti- Aβ therapies currently in development

4. CTS-21166 (CoMentis)

CTS21166 is an inhibitor of the second enzyme required to generate Aβ, β-secretase (BACE). The Phase I study indicated that CTS-21166 was safe and well , tolerated. A Phase II study is expected later this year. Like gamma-secretase, BACE does not only process APP, but processes several other important proteins as well. Thus, similar safety concerns as those mentioned for GSI's, above, may apply for this BACE inhibitor.

Outlook: Good. As long as the safety profile for BACE inhibitors holds up, this is a promising strategy for lowering cerebral Aβ levels.

Summary

In summary, one of our best chances for effectively treating and preventing AD based on what we have learned from the four established AD genes, so far, is to target the excessive accumulation of Aβ in the brains of AD patients with a cocktail of therapies that, on one hand, safely and specifically regulate Aβ production, and on the other hand, enhance the clearance of Aβ while also preventing its aggregation into neurotoxic forms (oligomers). With several active trials and other promising drugs headed toward trials, the hope is that at least one or more of these therapeutics will successfully slow or reverse disease progress in AD.

ALZHEIMER'S FOUNDATION OF AMERICA

Our mission is "to provide optimal care and services to individuals confronting dementia, and to their caregivers and families—through member organizations dedicated to improving quality of life."

Statement by Richard E. Powers, MD, Medical Advisory Board Chair
Alzheimer's Foundation of America

Hearing by the United States Senate Special Committee on Aging
"The Future of Alzheimer's: Breakthroughs and Challenges"

May 14, 2008

Chairman Kohl, Ranking Member Smith and distinguished Committee members:

On behalf of the Alzheimer's Foundation of America (AFA), thank you for holding this important hearing on "The Future of Alzheimer's: Breakthroughs and Challenges." We are pleased to submit this statement in support of the Committee's efforts to raise awareness about Alzheimer's disease in general, as well as AFA's efforts to promote early detection of memory problems and to serve as the national face of care for individuals and loved ones affected by the disease in particular.

Our Shared Mission

An estimated five million Americans currently have Alzheimer's disease, and the number is expected to rise to 16 million by mid-century. It is therefore critical that we all stand together for care as the incidence of this devastating disease continues to rise.

AFA (**www.alzfdn.org**) is a national, nonprofit 501(c)(3) organization that focuses on providing optimal care to individuals with Alzheimer's disease and related illnesses, and their families. While we hope for a cure, with none on the horizon, our objective is address the educational, emotional, medical, practical and financial needs of the millions of Americans dealing with the brain disorder on a daily basis, as well as to raise awareness of the disease and the needs of the dementia population through our own advocacy efforts and in collaboration with other organizations.

We achieve these goals through myriad programs and services available at our national headquarters in New York—such as a toll-free hotline, counseling by licensed social workers, bilingual educational materials, respite care grants and a free caregiver magazine—and groundbreaking national initiatives spearheaded by AFA, including the AFA Quilt to Remember, Dementia Care Professionals of America, and National Memory Screening Day as part of a wide-ranging campaign to promote early diagnosis and treatment. In addition, we unite 900+ member organizations nationwide that provide hands-on programs and services in local communities that help improve quality of life for those with the disease and their families; these organizations continue to operate independently while benefiting from being part of a larger network, including the opportunity for nonprofit members to apply to AFA for grants to develop or enhance programs and services in their local communities.

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The Importance of Early Detection

AFA is the leading advocacy organization for promoting early detection of Alzheimer's disease and related dementias through memory screening. One of the main arguments in favor of memory screening is that there are serious deficiencies in the health care system's ability to recognize dementia. A 2006 editorial in the *Journal of the American Geriatric Society* estimated that missed diagnoses are greater than 25 percent of the dementia cases and may be as high as 90 percent.[1] Not surprisingly, individuals with mild dementia are more likely to go unrecognized by physicians and family (more than 90 percent) than persons with moderate to severe dementia (more than 70 percent); however, researchers agree that those with early disease are best treated with available medications.[2-3-4] In addition, while close friends and family can play an important role in detection of dementia, many elderly live alone and have limited contact with distant relatives or friends.

There are additional barriers[5] to early detection[6] of dementia:

- Individuals are often unaware, deny, or minimize the severity of symptoms or are concerned about stigma
- Evaluation may be time consuming and not well reimbursed
- Many, especially ethnic populations, believe that memory loss and cognitive decline are a normal part of aging

In addition, most people are not inclined to discuss memory concerns with their doctors. A survey conducted during AFA's 2006 National Memory Screening Day found that 73 percent of respondents had concerns about their memory. However, while more than 80 percent had visited their primary care physician within the last six months, fewer than one in four of those with self-identified memory problems had discussed the issue with their physician.[7]

A memory screening is a simple and safe evaluation tool that assesses memory and other intellectual functions and indicates whether additional testing is necessary. Memory screening can be done in a medical environment (e.g. dementia clinic, physician's office), or in a community setting (e.g. senior center, pharmacy).

Several screens have adequate sensitivity (probability of true positives) and specificity (probability of true negatives) to serve as routine, cost-worthy evaluations. In fact, validated memory screening instruments demonstrate 80-90 percent or higher sensitivity and specificity in reviewed studies[8]—similar to other established screening tests such as mammography[9] and Pap smear.[10] The major considerations in choosing a screening test are practicality and applicability in settings in which older adults receive their care.

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[8] Solomon PR, Murphy CA, "Should we screen for Alzheimer's disease? A review of the evidence for and against screening for Alzheimer's disease in primary care practice," *Geriatrics* 2005, 60(11): 26-31.
[9] See National Cancer Institute, "Breast Cancer Screening Modalities," at http://www.nci.nih.gov/cancertopics/pdq/screening/breast/HealthProfessional/page5

Screening should be targeted at those with memory concerns and those with sufficient risk to warrant the testing. The most central risk factor for Alzheimer's disease is age. Based on the fact that the incidence of dementia doubles every five years between 65 and 95, some experts recommend that annual memory screening is beneficial for everyone over 75, and for people over 65 with a family history or other risk factors.[11]

The main argument against memory screening is that there are many potential adverse consequences with both positive and negative results. However, **screening is neither a diagnostic or case finding process.** Screening tests in general simply help determine whether diagnostic tests should be considered. A "positive" result from a memory screening should never be interpreted as a diagnosis of Alzheimer's disease or related illness—no more than a "positive" mammogram means an individual has breast cancer. It is oversimplifying to apply the potential adverse consequences of diagnostic interventions to the use of a brief check for early dementia signs for triggering a complete evaluation.[12]

National Memory Screening Day

Memory screenings are one of the major focal points of the AFA's national initiatives. For the past five years, AFA has sponsored National Memory Screening Day (NMSD) annually in collaboration with community organizations to promote early detection of memory problems as well as Alzheimer's disease and related illnesses, and encourage appropriate intervention. In November 2007, qualified health care professionals at more than 2,000 sites nationwide offered free confidential memory screenings to an estimated 50,000 participants, as well as follow-up resources and educational materials about dementia and successful aging.

Qualified health care professionals—including social workers, pharmacists, physician assistants, nurse practitioners, and doctors—provide the screenings. The face-to-face screening takes place in a private setting in such venues as Alzheimer's agencies, senior centers, long-term care facilities, doctors' offices and pharmacies; only the individual being tested and the clinician are present. The screening usually takes less than 15 minutes on average and consists of a series of questions and/or tasks designed to test memory, language skills, thinking ability, and other intellectual functions.

A memory screening is not used to diagnose any particular illness and does not replace consultation with a qualified physician or other health care professional. The person who administers the screening reviews the results with the person screened, and suggests whether follow up with a physician or other health care professional for more extensive testing is necessary. Those with abnormal scores and those who still have concerns are encouraged to pursue further evaluation. The person who was screened will receive the screening results to bring to their health care professional. Screening sites also provide information about successful aging, including the benefits of proper diet, physical exercise, mental stimulation, socialization, and stress management.

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[12] Ashford JW, Borson S, O'Hara R, Dash P, Frank L, Robert P, et al, "Should older adults be screened for dementia? It is important to screen for evidence of dementia," *Alzheimer's & Dementia* 2007;3:75-80.

The Benefits of Early Detection

Recognition of impairment benefits two people; the patient and the person receiving care.[13] Early identification of at-risk patients provides multiple benefits to the individual, the caregiver, the family, and society. For the affected individual, identification of early stage dementia allows early aggressive use of available treatments. Early stage patients can be offered support groups to diminish the psychological impact of the disorder. Most patients, regardless of their degree of impairment, tend to experience a sense of relief after receiving their diagnosis.[14] Moreover, the total medical care for this individual can be adjusted to meet the needs of a cognitively impaired patient. Issues such as patient education, self-medication, compliance, and hospital care can be adjusted to meet the needs of a mildly demented person who is at risk for common complications such as delirium and depression. The early identification of dementia supports individual patient rights and self-determination. Most mildly impaired patients are capable of charting the future course of their care and making substantial decisions on issues like end-of-life care, resuscitation, disposition of wealth, etc. Informing at-risk patients about abnormal screening does not produce hardship or harm to the patient or family caregiver.[15–16–17–18–19]

About one-third of elders live by themselves and these individuals are at risk for accidents, injuries, exploitation, and other adverse outcomes. Early identification allows safeguards and home assistance to assure continued maximization of home placement. Family caregivers derive multiple benefits from early identification. Early identification may reduce the burden of later life decision-making on issues like resuscitation, disposition of wealth, long-term care, etc. as families can solicit the opinion of the patient while still competent.

Screening and early identification may benefit society by protecting individuals and reducing costs of health care. Unrecognized dementia can increase the likelihood of avoidable complications such as delirium, adverse drug reactions, noncompliance, etc. These complications can reduce the autonomy of the patient. Enhancing compliance and protecting demented patients has obvious financial benefits to the health care system. Published studies on screening for community-based elders demonstrate effectiveness and acceptance.[20–21–22]

Memory screenings can also serve as an important first step toward detecting reversible conditions that cause memory loss, such as vitamin deficiencies, depression or thyroid problems. Screenings also can let people know when they are okay. For persons with a normal screen, a memory screening provides a valuable opportunity to promote cognitive wellness and successful aging similar to those underway in other nations, such

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[22] Turnbull Q, Wolf AMD, Holroyd S. Attitudes of elderly subjects toward "truth telling" for the diagnosis of Alzheimer's disease. *J Geriatr Psychiatry Neurol* 2003;16:90-93.

as Japan.[23–24] A simple, direct, cognitive wellness message can be presented to these individuals that may reduce their likelihood for developing dementia at a later age. The emotional boost from a normal dementia screen can be used as an opportunity to discuss basic, preventive interventions such as compliance with anti-hypertensives, responsible drinking, intellectual stimulation and other recommendations that may further protect a patient's cognitive function.[25–26] .

The benefits to elders are clear. Individuals with dementia can receive available therapy when identified and diagnosed. The health care management can be adjusted to incorporate treatment strategies that accommodate a person with cognitive impairment. Home-based support systems can be adjusted to maximize home placement for this person.[27] Safeguards can be taken to prevent avoidable complications such as delirium during hospitalization. Advanced directives can be discussed that incorporate the wishes of the individuals and reduce the burden of surrogate decision making for the family. Available treatments for Alzheimer's disease and other forms of dementia are most helpful in the early stages of illness. Early identification allows optimal therapy with available and emerging medications.

It is widely recognized that physicians do not suspect dementia often enough, missing at least half the cases of mild and moderate dementia. Recognition of dementia by primary care physicians is poor until it is at least moderately advanced. There is ample evidence that screening can improve case identification,[28] leading to the suggestion that community screening could double the number of patients eventually diagnosed with dementia.[29–30–31] Only the implementation of screening programs can rectify this failure of current diagnostic practices.

The Need for a National Policy

Presently, there is no national policy on dementia screening. Despite the acceptable accuracy of screens as well as the availability of medications for early to advanced stages of the disease, there is no public health policy on assessing for dementia.

The present Medicare screening and prevention program does not include cognitive function. However, the Centers for Medicare and Medicaid Services (CMS) did decide to include screening for cognitive impairment within the scope of its Initial Preventive Physical Exam (IPPE), commonly known as the "Welcome to Medicare" exam. The Final Rule specifically recognizes that "review of the individual's functional ability and level of safety" would include an assessment of the role cognitive impairment may play in affecting an individual's ability to perform activities of daily living.

A national system of dementia screening will require several years for development and implementation. A flexible array of services and instruments will be required. A policy executed today would only be fully

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available in the field several years from now. Local organizations are left to create their own programs without assistance or guidance.

Scientists and researchers are trained to accept treatment strategies that incorporate evidence-based practices. Although, this conceptual model is the gold standard, this strategy has significant limitations that are rarely emphasized by the scientific community. Mass scale public health interventions are tested over a multi-decade period. Researchers are generally preoccupied with conclusive scientific data and the promotion of research. In contrast, public systems must use a pragmatic approach, i.e., "best possible solution."

AFA's Policy Recommendations

AFA respectfully recommends that Congress and the Administration work collaboratively to adopt the following changes in national policy regarding dementia screening:

- ✓ National leadership should recognize the role of early intervention for the success of available medical, psychological, and social interventions for dementia. The value of early recognition extends beyond the opportunity for treatment to improving patient autonomy, adjusting health care services and supporting family caregivers.
- ✓ Dementia screening should be used as an opportunity to promote cognitive wellness among elders.
- ✓ CMS should provide clear guidance to providers and beneficiaries regarding: (1) the circumstances under which screening for cognitive impairment should be conducted; and (2) the extent of Medicare's coverage for services provided in the context of the IPPE or any medically necessary follow-up examination. Such an initiative can be seamlessly incorporated into the agency's broader efforts to inform beneficiaries and providers about the IPPE.[32] Ideally, CMS should cover a baseline memory screening for all new Medicare beneficiaries.
- ✓ A consensus panel can craft recommendations on screening using members that includes a broad range of consumers as well as scientists and experts.
- ✓ Policymakers should encourage medical schools to include in their curriculum recognition of and treatment for memory problems in general, and Alzheimer's disease and related dementias specifically. Such curricula should also seek to train students on dementia-related racial and ethnic health disparities.
- ✓ Medical school loan incentives should be created to encourage entry into the geriatric field.
- ✓ Policymakers should acknowledge the importance of research; however, the country needs a balanced program that prepares aging baby boomers for evolving and future therapies.
- ✓ Policymakers should request a review by the Institute of Medicine to examine current research programs and provide a timetable for when an Alzheimer's disease "cure" is likely to be developed and what it will look like.
- ✓ The National Institute on Aging (NIA) should fund research to compare existing memory screening tools to identify those that are most useful.

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[32] Failure to effectively communicate this information will have severe consequences for affected Medicare beneficiaries. Unrecognized dementia can increase the likelihood of avoidable complications such as delirium, adverse drug reactions, and noncompliance with a prescribed medication regimen. These complications reduce the autonomy of affected patients, thereby impeding their ability to perform activities of daily living and compromising their safety. Such an outcome would be inconsistent with the relevant American Academy of Neurology practice guideline for physicians, which states: "Patients with mild cognitive impairment should be recognized and monitored for cognitive and functional decline due to their increased risk for subsequent dementia." Similarly, the U.S. Preventive Health Services Task Force has concluded that while "current evidence does not support routine screening of patients in whom cognitive impairment is ***not*** otherwise suspected, clinicians should assess cognitive function whenever cognitive impairment or deterioration ***is*** suspected, based on direct observation, patient report, or concerns raised by family members, friends, or caretakers." (Emphasis added)

✓ NIA should fund research to help develop a more effective method of case-finding for dementia and for earlier detection in particular.

The absence of prospective data on the effectiveness of screening has limited the willingness of experts to promote a specific plan of action for screening. Programmatic issues such as age at which screening should be initiated, frequency of screening, successful aging information, types of expected counseling available to persons who trigger concerns about cognitive decline, methods of dealing with persons who exhibit age-associated memory impairment, or mild cognitive impairment, and other key issues can be defined by a consensus panel that includes experts, public health officials, consumers, and advocates. Academic centers are unlikely to initiate this program. Congress or the Administration on Aging can convene a national consensus conference to set parameters for screening. Specific outcomes measures can be discussed although sufficient data presently exists to affirm the safety, accuracy and value of dementia screening.

The screening process provides an opportunity to disseminate material on successful aging and cognitive wellness in elders. Our nation needs a specific set of recommendations to promote intellectual health in aging individuals. Sufficient data exists to craft these guidelines for both consumers and physicians. AFA and affiliated organizations presently disseminate information that is based on peer-reviewed published literature. These guidelines can be amended and improved over time; however, our nation needs a starting point for this wellness program. This policy should be crafted using experts as well as public health, experts, consumers, and advocates. Congress should initiate this process to promote prevention and wellness among elders.

Conclusion

AFA commends the Committee's leadership on these issues. We greatly appreciate your consideration of our views and look forward to working with you to accomplish shared policy objectives. In summary:

- Most persons with dementia remain undiagnosed by their primary care physicians, and families often fail to appreciate the significance of early cognitive symptoms.
- The screening of at-risk populations for dementia should become a cornerstone for early treatment or prevention of cognitive decline in older people.
- Prospective prevention research will not be performed in a timely manner to confirm the value of screening and policy makers must propose the best possible option as a comprehensive approach to cognitive health in elders.
- Screening is not a diagnosis, but can help lead to referral of appropriate individuals to clinicians for further evaluation or promotion of cognitive wellness for normal elders.
- Screening does not produce adverse outcomes and published screening instruments can be completed in as little as five minutes. Screening is a safe, cost-efficient intervention that can reassure the healthy elder, promotes successful aging, and directs at-risk individuals to appropriate clinical resources.
- Currently, there is no national policy on dementia. It is irresponsible to leave the disease undetected to the extent it is now when there are safe tools available to increase earlier detection. There are several policy recommendations that, if implemented, would assist clinical efforts at early diagnosis and treatment for dementia.

US Senate Special Committee on Aging Hearing May 14, 2008

The Future of Alzheimer's: Breakthroughs and Challenges

My name is Richard Grimes, CEO & President of the Assisted Living Federation of America. I would like to thanks Senator Kohl and Senator Smith for holding this important hearing. Ironically I am unable to attend the hearing in person because my stepmother, a victim of Alzheimer's recently passed away. In a story that parallels Justice O'Connor, after years of taking care of my stepmother at home, feeding her, dressing her, bathing her, my 89 year old father helped move her into an assisted living community where she could get quality professional care and attention, until her recent death. I appreciate the opportunity to submit the following remarks for the record.

Scientists estimate more than 14 million Americans will suffer from Alzheimer's disease in the next 40 years and half of all people who reach the age of 85 will exhibit some symptoms of the condition. While drugs can slow the progression of the disease, there is no cure.

The federal government says more than 4.5 million Americans are afflicted with Alzheimer's disease today. This devastating progressive brain disease robs individuals of personality, memory and the ability to communicate. Some exhibit behavior problems, even becoming violent, which make it impossible for them to live alone or with family members. Those with Alzheimer's live an average eight to ten years after the diagnosis, some live as long as 20 years. The stress and strain on family caregivers can be overwhelmingly.

Assisted living providers offer a safe and comfortable option for Alzheimer's suffers. The Assisted Living Federation of America, the trade association representing the nation's leading assisted living providers, is proud of the ground breaking work of its members in creating a humane and secure living environment for the victims of this dreaded disease.

Assisted living is the fastest growing long term care option in the United States because industry providers work aggressively to meet the needs of an aging population. More than one million seniors live in assisted living communities in the United States and surveys consistently report satisfaction levels at an enviable 90 plus percentage points.

This relentless focus on meeting customer needs and desires in a homelike residential setting has led to tremendous innovation in caring for individuals with Alzheimer's and other forms of dementia. At one time, the only prescription for an individual with severe Alzheimer's was heavy doses of psychotropic drugs in a nursing home setting. No longer.

Our members offer a variety of care models. Some of our members, such as Silverado Senior Living of San Juan Capistrano, California, specialize in the care of residents with Alzheimer's and other forms of dementia. Others, like Benchmark Assisted Living of Wellesley, Massachusetts, operate communities which provide specialized care for the memory impaired. Many of our members, including Sunrise Senior Living of McLean, Virginia and Brookdale Senior Living Inc. of Chicago –the two largest assisted living providers in the nation-- offer Special Care neighborhoods, separate wings of assisted living communities, for their residents with Alzheimer's and related dementia. Sunrise offers multiple levels of support from the earliest stages of memory loss to Reminiscence Neighborhoods for those with more severe symptoms to special intimate suites for those in the latter stage of the disease.

As residential and service providers on the front lines of care, our members have helped create and refine the modalities and standards of care for these residents in a non-institutional setting. They include:

- Care models and sensitivity to individual routines that significantly reduce behavior problems often seen among those suffering from various forms of dementia resulting in reduced use of anti-psychotic and anti-anxiety drugs
- Rapid implementation of cutting edge study results For example, assisted living providers routinely encourage exercise and physical activities for residents which recent studies show reduces the level of dementia in seniors.
- Use of new technology. The Alzheimer's residents at many assisted living communities wear GPS tracking devices that allow them to walk freely on the grounds but keep them from dangerous wandering.
- Creation of secure and homelike living spaces with wall to wall carpeting, secure outdoor walkways and waist high gardening beds.
- Specialized training for staff to provide compassionate care for these residents.

Assisted living is a particularly appropriate setting for seniors with this disease because it evolved as a model of care which respects the choice, dignity and independence of a frail adult. The philosophy of assisted living is to create a residential setting that allows frail seniors to live independently and safely in private rooms or apartments while providing the support each individual needs. Services range from help with personal hygiene and grooming, showering and bathing and assistance with eating and dressing. The typical assisted living resident is an 83 year old widow. The Alzheimer's Association estimates that more than half of assisted living residents suffer from some form of dementia.

The pernicious nature of dementia as a symptom of normal forgetfulness sometimes makes it difficult to make judgments about the mental capacity of an elderly man or woman to live independently. Our members often find themselves helping family members with a frail senior determine the best place to live. It is never easy but the assisted living industry is thriving because of its compassion and respect for residents, and the quality of care provided. Assisted living is a choice that helps seniors age in place with dignity and enhances the quality of their lives.

David W. Wright, M.D., F.A.C.E.P.

Dr. Wright is Assistant Professor of Emergency Medicine and Co-Director of Research at Emory University. He obtained his undergraduate degree from Samford University and his medical training from the University of Alabama at Birmingham. During medical school, he spent a year and half conducting basic molecular and cell biological research as a Howard Hughes Fellow. This work led to the first detailed images of the fibrillin molecule, whose abnormal structure or absence causes Marfan's syndrome. In 1997, Dr. Wright completed residency training in Emergency Medicine at the University of Cincinnati and joined the faculty in the Department of Emergency Medicine at Emory University. Shortly after arriving, he began to focus on neuroinjury research. On the strength of his promise as a researcher, he was the first emergency physician in the country selected to receive the Society for Academic Emergency Medicine's "Scholarly Sabbatical" award. He is the principal investigator for NIH funded basic science research projects. This work led to ProTECT™, a National Institutes of Health (NIH) funded clinical trial, designed to assess progesterone as a neuroprotectant following acute traumatic brain injury (TBI). With NIH funding, he is currently planning ProTECT™ III the world's first large scale clinical trial of this treatment. In addition, he is conducting collaborative research with the Georgia Institute of Technology to develop new technologies for detecting cognitive impairment resulting from mild TBI and early Alzheimer's disease. Dr. Wright has won several awards for research excellence from the Society of Academic Emergency Medicine and was the recipient of the 2008 Health Care Heros Award from the Atlanta Business Chronicles. He continues to be an active clinician, educator and researcher.

Proposed TESTIMONY

Mr. Chairman, Committee Members, thank you for the opportunity to enter this information into the record on Alzheimer's Disease. The purpose of this testimony is to promote more research into early detection of Alzheimer's disease. I am Dr. David Wright M.D., Assistant Professor and Director for Research, Department of Emergency Medicine at Emory University.

As a medical doctor, I am concerned that Alzheimer's disease usually goes undiagnosed until it is in its moderate or severe stages. Early detection provides the best opportunity for designing and testing new strategies to halt the disease. In addition, early detection allows patients and their families to make informed decisions and plans to enhance their safety and independence. We also believe the early detection provides the maximum opportunity for the current drugs (which delay symptom onset) to have an effect and thereby allow patients to be more independent for a longer period of time. This is critical to both the quality of life and the reducing the long-term care cost for patients and their family.

In its earliest form, Alzheimer's presents as mild cognitive impairment (MCI). MCI is characterized by a subtle loss of memory that is difficult for the primary care physician to detect. Moreover, most primary care physicians do not regularly assess patients' "cognitive function" in check ups or annual visits, in part because of the lengthy time required, insufficient insurance reimbursement limits, and because no tools exist that can reliably detect impairment. As a consequence, MCI often goes undiagnosed until more overt signs and symptoms of Alzheimer's disease are present. There is an urgent need for better methods and tools to detect MCI and Alzheimer's disease.

At Emory University and the Georgia Institute of Technology, we have been conducting research into better methods to detect the earliest signs of Alzheimer's disease. There are many research avenues being pursued, ranging from quick screens that are practical to conduct in the primary care office to sophisticated brain PET imaging methods that directly measure amyloid deposits. We have made substantial progress in many of these areas, but more focus and funding is urgently needed. Moreover, there is a critical need for a systematic push at all levels to insist on early screening in the primary care setting (starting at the approximate age of 50) as a routine part of a normal clinical evaluation.